**SUBJECT:** Immunization-Pandemic Influenza Mass Vaccination

#### **POLICY STATEMENTS:**

- 1. Pandemic influenza mass vaccination will occur when an agency directive for a mass vaccination project is issued by the Commissioner (or his/her designee).
- 2. DHEC will provide pandemic influenza vaccine services ensuring that vaccine is administered in an efficient and timely manner to those requiring vaccine.
- 3. DHEC will follow CDC/Health and Human Services recommendations for the use of pandemic influenza vaccine regarding populations to be vaccinated and specific contraindications to vaccination (see *Appendix A, HHS Vaccine Priority Group Recommendations*).
- 4. In conjunction with DHEC Immunization Division, each DHEC Public Health Region will be responsible for regional pandemic influenza mass vaccination clinic operations. Operational components include:
  - a. Immunization strategies for vaccination of priority groups
  - b. Acquisition, storage, safeguarding, cold-chain management and disposal
  - c. Security
  - d. Identification of pandemic influenza mass vaccination facilities and establishment of Memorandum of Agreement (MOA) (see *Appendix B, MOA for Pandemic Influenza Mass Vaccination Facilities*)
  - e. Recruitment and enrollment of vaccine providers/staff for mass vaccination clinic and establishment of Memorandum of Agreement (MOA) (see *Appendix C-1, MOA for DHEC Pandemic Influenza Mass Vaccination Clinic Vaccine Providers and Staff and C-2 Volunteer Health Professional Agreement*)
  - f. Recruitment and enrollment of vaccine providers at private offices/institutions for provision of vaccination services and establishment of Memorandum of Agreement (MOA) (see Appendix D, MOA for Private Pandemic Influenza Vaccine Providers)
  - g. Immunization Documentation (see *Appendix E, Pandemic Influenza Vaccination Form*)
  - h. Vaccine adverse event monitoring and response system (VAERS) (see *Appendix F, VAERS Training Module and Appendix G, VAERS Reporting Form/Instructions*)

- 5. Personnel reassignments from routine DHEC services will occur in order to provide necessary staff for mass vaccination clinics.
- 6. Documentation of pandemic influenza vaccine administration will be required in accordance with <a href="Immunization Documentation">Immunization Documentation</a> Policy and Procedure. Documentation will be considered a medical record and will be batch filed in accordance with DHEC guidelines.
- 7. DHEC will coordinate pandemic influenza activities with bordering states as indicated.

#### LAWS AND REGULATIONS:

- S.C. Code of Laws §44-29-210. Physicians, Registered Nurses and certain authorized Public Health Employees participating in Mass Immunization Projects exempt from liability exceptions.
- S.C. Code of Laws §44-1-110. Duties of Department in Regard to Public Health, In General.
- S.C. Code of Laws §§44-4-100 to 570. Emergency Health Powers Act
- S.C.Code of Laws §44-1-80. Duties and Powers of Board as to Communicable or Epidemic Diseases
- S.C. Code of Laws §44-1-140. Department May Promulgate and Enforce Rules and Regulations for Public Health
- S.C. Code of Laws §44-29-10. Physicians and County Health Departments Shall Report Contagious and Infectious Diseases.
- S.C. Code of Laws §44-29-40. Department of Health and Environmental Control Shall Have General Supervision of Vaccination, Screening, and Immunization.

#### **STANDARDS:**

- 1. DHEC Immunization Division will follow CDC recommendations for the acquisition and distribution of pandemic influenza vaccine.
- 2. DHEC Immunization Division will be responsible for overall management of pandemic influenza vaccine.

- 3. DHEC Immunization Division will provide guidance regarding proper storage, safeguarding, cold-chain management and disposal of pandemic influenza vaccine.
- 4. Each DHEC Public Health Region will be responsible for storage, safeguarding, cold-chain management, and disposal of pandemic influenza vaccine.
- 5. Each DHEC Public Health Region Mass Casualty Response Plan must incorporate and implement all elements of the DHEC Pandemic Influenza mass vaccination policies and procedures.
- 6. Pandemic influenza vaccination standing orders will be developed and implemented for non-Investigational New Drug (non-IND) and for each Investigational New Drug (IND) vaccine as needed. Standing orders will contain indications, contraindications and treatment orders for pandemic influenza vaccination.
- 7. Pandemic influenza vaccination standing orders will be developed and implemented for Emergency Use Authorization Drug, as needed.
- 8. Each DHEC Public Health Region will be responsible for identifying personnel, location and equipment necessary for the operation of Pandemic Influenza mass vaccination clinics.
- 9. All DHEC staff and DHEC volunteers will follow the DHEC Pandemic influenza vaccination standing orders.
- 10. During mass vaccination clinic(s), clinic staff will identify and separate individuals with known exposure to pandemic influenza or symptomatic for pandemic influenza.
- 11. All personnel who will participate in mass vaccination clinics will be vaccinated as recommended by the CDC. Participation is defined as any person assigned to a job action sheet (see Appendix K).
- 12. Each DHEC Public Health Region Mass Casualty Plan must incorporate plans to reach populations less likely or able to seek vaccination.

#### **PROCEDURES:**

#### A. Immunization Strategies

Several Immunization Strategies will be considered by DHEC based on CDC guidance and vaccine supply.

1. Immunization Strategies for HHS Priority Groups

#### Tier 1A

- Vaccine and antiviral manufacturers and others essential to manufacturing and critical support
- Medical workers and public health workers who are involved in direct client contact, other support services essential for direct client care, and vaccinators (this is inclusive of federal healthcare providers to Indian nations and tribes).
- 1. Identification of all potential vaccinees is required. Each vaccine and antiviral manufacturer, medical care facility and public health facility involved in the pandemic influenza response must document priority group status of potential vaccinees. If persons are to be vaccinated by DHEC, the list of critical staff that will need vaccination must be provided to the DHEC Public Health Region's Immunization Program Manager in advance.
- Determine whether each institution can vaccinate identified persons in their facility. DHEC will arrange for vaccine distribution to each institution.
- 3. Each DHEC Public Health Region must establish MOAs with institutions providing vaccinations. Included in the MOA must be agreement to abide by HHS priority groups and documentation/reporting requirements.
- 4. If institution unable to provide vaccination, DHEC will vaccinate critical staff. Each individual must bring their identification to be matched with documentation of priority group provided by each institution.

#### Tier 1B

- Persons <u>></u> 65 years with one or more influenza high-risk conditions, not including essential hypertension.
- Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertention.
- Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year
- 1. Vaccination at Medical Home
  - a. An MOA with the medical home must be established to receive vaccine. Included in the MOA must be agreement to abide by HHS priority groups.

- b. Documentation of priority status of all potential vaccinees is required. Refer to Section 2 – Acceptable Options for Documentation of Priority Group Status.
- c. DHEC will supply the required vaccine to the medical home, as available. VAFAC distribution system will be used for eligible children/adolescents.

#### 2. Vaccination at DHEC Clinics

- a. All potential vaccinees who cannot receive vaccination at medical home will receive vaccine at DHEC clinic.
- b. Vaccinees will be required to provide identification and documentation of their priority group as Tier 1B. Prescription instructions will be provided to medical providers.
- c. If documentation is not available, potential vaccinee will need to provide evidence of priority status as Tier 1B.

#### Tier 1C

- Pregnant women
- Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine
- Household contacts of children < 6 months old</li>
- Vaccination at Medical Home Pregnant Women, Severely Immunocompromised Persons and Household contacts of children < 6 months of age
  - a. An MOA with the medical home must be established to receive vaccine. Included in the MOA must be agreement to abide by HHS priority groups.
  - b. Documentation of priority status and identification of all potential vaccinees is required.
  - c. DHEC will supply the required vaccine to the medical home, as available. VAFAC distribution system will be used for eligible children/adolescents.

#### 2. Vaccination at DHEC Clinics

- a. All potential vaccinees who cannot receive vaccination at medical home will receive vaccine at DHEC clinic
- b. Vaccinees will be required to provide documentation of priority groups status for Tier 1C and identification.
- c. If documentation is not available, potential vaccinee will need to provide evidence of priority status as Tier 1C.

#### Tier 1D

- Public health emergency response workers critical to pandemic response
- Key government leaders
- Identification of all potential vaccinees is required. All agencies critical
  to providing Public Health Emergency response workers must provide
  DHEC designee with a list of critical staff who will need vaccination. A
  list of key government leaders must be provided by State and county
  governments.
- 2. Determine whether each agency can vaccinate identified persons in their facility. DHEC will arrange for vaccine distribution to each agency.
- 3. Each DHEC Public Health Region must establish MOAs with agencies providing vaccinations. Included in the MOA must be agreement to abide by HHS priority groups.
- 4. If agency unable to provide vaccination, DHEC will vaccinate critical staff. Each individual must bring documentation of priority status for Tier 1D and identification.

#### Tier 2A

- Healthy 65 years and older
- 6 months to 64 years with one high-risk condition
- 6-23 months old, healthy
- 1. Vaccination at Medical Home 6 months to 64 years of age with one high-risk condition
  - a. An MOA with the medical home must be established to receive vaccine. Included in the MOA must be agreement to abide by HHS priority groups.
  - b. Documentation of tier group 2A status and identification of all potential vaccinees is required.
  - c. DHEC will supply the required vaccine to the medical home, as available. VAFAC distribution system will be used for eligible children/adolescents.
- 2. Vaccination at DHEC Clinics 6 months to 64 years of age with one high-risk condition
  - a. All potential vaccinees who cannot receive vaccination at medical home will receive vaccine at DHEC clinic
  - b. Documentation of tier group 2A status and identification of all potential vaccinees is required.
  - c. If documentation is not available, potential vaccinee will need to provide evidence of priority status as Tier 2A.

- 3. Vaccination at Medical Home Healthy 6-23 months and 65 years of age and older
  - a. An MOA with the medical home must be established to receive vaccine. Included in the MOA must be agreement to abide by HHS priority groups.
  - b. Identification of all potential vaccinees is required
  - c. DHEC will supply the required vaccine to the medical home, as available. VAFAC distribution system will be used for eligible children/adolescents.
- 4. Vaccination at DHEC clinic Healthy 6-23 months and 65 years of age and older
  - a. All potential vaccinees who cannot receive vaccination at medical home will receive vaccine at DHEC clinic
  - b. Documentation of tier group 2A status and identification of all potential vaccinees is required (persons  $\geq$  18 years will need photo identification).
  - a. If documentation is not available, potential vaccinee will need to provide evidence of priority status as Tier 2A.

#### Tier 2B

- Other public health emergency responders
- Public safety workers including police, fire, 911 dispatchers, and correctional facility staff
- Utility workers essential for maintenance of power, water, and sewage system functioning
- Transportation workers transporting fuel, water, food, and medical supplies as well as public ground transportation
- Telecommunications/IT for essential network operations and maintenance
- 1. Identification of all potential vaccinees is required. All agencies critical to providing Public Health Emergency response workers, public safety workers, utility workers, transportation workers and telecommunications workers must provide a list of critical staff to DHEC who will need vaccination.
- 2. Determine whether each agency can vaccinate identified persons in their facility. DHEC will arrange for vaccine distribution to each agency.
- 3. Each DHEC Public Health Region must establish MOAs with agencies providing vaccinations. Included in the MOA must be agreement to abide by HHS priority groups.
- 4. If agency unable to provide vaccination, DHEC will vaccinate critical staff. Each individual must bring documentation of priority status for Tier 2B and identification.

#### Tier 3

- Other key government health decision-makers
- Funeral directors/embalmers
- 1. Identification of all potential vaccinees is required. All funeral directors/embalmers must provide a list of critical staff to DHEC who will need vaccination. A list of other key government leaders must be provided by State and county governments.
- 2. Determine whether each agency can vaccinate identified persons in their facility. DHEC will arrange for vaccine distribution to each agency.
- 3. Each DHEC Public Health Region must establish MOAs with agencies providing vaccinations. Included in the MOA must be agreement to abide by HHS priority groups.
- 4. If agency unable to provide vaccination, DHEC will vaccinate critical staff. Each individual must bring documentation of priority status for Tier 3 and identification.

#### Tier 4

- Healthy persons 2-64 years not included in above categories
- 1. Vaccination at Medical Home Healthy persons 2 to 64 years of age not included in the previous categories
  - a. An MOA with the medical home must be established to receive vaccine. Included in the MOA must be agreement to abide by HHS priority groups.
  - b. Identification of all potential vaccinees is required.
  - c. DHEC will supply the required vaccine to the medical home, as available. VAFAC distribution system will be used for eligible children/adolescents.
- 2. Vaccination at DHEC Clinics Healthy persons 2 to 64 years of age not included in the previous categories
  - a. All potential vaccinees who cannot receive vaccination at medical home will receive vaccine at DHEC clinic
  - b. Identification of all potential vaccinees is required.
- 2. Acceptable Options for Documentation of Priority Group Status
  - 1. Vaccinees with specific medical risk factors, including pregnancy (one copy of the following must be presented to DHEC Immunization Clinic)
    - a. Prescription from medical home listing age, risk factors and HHS priority tier group status.

- i. Instructions for completing the prescription will be provided by DHEC
- b. Form for Documentation of Priority Tier Groups (see *Appendix E, Pandemic Influenza Vaccination Form*)
- 2. Healthy vaccinees in specific age groups
  - a. Proof of age.
- 3. Vaccinees in priority groups needed for pandemic influenza response
  - a. List of potential vaccinees in each priority group status to be provided by agency/institution.

## B. Pandemic influenza vaccine acquisition, storage, safeguarding, cold-chain management, and disposal

- 1. Overall Management
  - a. Each DHEC Public Health Region's Immunization Program Manager will serve as point of contact with the DHEC Immunization Division.
  - b. Each DHEC Public Health Region will designate a mass vaccination clinic Supply Manager for the overall management of all aspects of pandemic influenza vaccine.
  - c. Chain-of-custody procedure for management of pandemic influenza vaccine will be followed (see *Appendix H—Pandemic Influenza Vaccine Chain of Custody/Temperature Monitoring Form*)
  - d. Each DHEC Public Health Region will be responsible for obtaining essential supplies and equipment necessary for vaccine storage, safeguarding, cold-chain management and disposal.
  - e. DHEC Public Health Regional responsibilities should be specified in their Mass Casualty Plan.
- 2. Pandemic influenza vaccine will be acquired and distributed per CDC recommendations.
  - a. DHEC's Immunization Division director or designee will coordinate with the public health regional vaccine manager and/or designee regarding security for acquisition, storage and delivery of vaccine to each public health region.
  - b. DHEC's Immunization Division director or designee will coordinate shipment of vaccine with each public health region and/or private sector as indicated. (see Appendix I Pandemic Influenza Vaccine Order Form).
  - c. An authorized record will be established and maintained for each vaccine vial(s) during transport (see *Appendix H Pandemic Influenza Vaccine Chain of Custody/Temperature Monitoring Form*).

- 3. Safeguarding, Storage, Transport and Cold Chain Management
  - a. All vaccine vials will be accounted for at all times and secured in a locked storage area while not in use.
  - b. Within the Chain-of-Custody process, cold chain management must be followed.
  - c. The public health regional vaccine manager and/or designee will be responsible for the following:
    - i. Receive and sign for the vaccine.
    - ii. Transport vaccine to designated sites in an appropriate storage unit as specified by the CDC.
    - iii. Record the storage unit temperature readings at the beginning of vaccine transport and when the vaccine reaches its destination.
    - iv. Monitor the cold-chain at all times and record temperatures twice daily regardless of the method used for transport or storage of the vaccine. A continuous temperature-recording device is preferred for cold-chain monitoring. (See Appendix J, *Pandemic Influenza Vaccine Temperature Log/Instructions*).
  - d. The public health regional supply manager and/or designee is required to record the temperature of the storage unit at the time of vaccine transfer from the storage transport container to the designated storage unit.

#### C. Mass Vaccination Clinics

- 1. Overall Management
  - a. Each DHEC Public Health Region must enter into Memorandum of Agreement (MOA) with appropriate entities for necessary staff and appropriate vaccination sites/facilities.
  - b. All MOAs must be included in each region's Mass Casualty Response Plan (see Appendix B, MOA for Pandemic Influenza Mass Vaccination Facilities; Appendix C-1, MOA for DHEC Pandemic Influenza Mass Vaccination Clinic Vaccine Providers and Staff; Appendix C-2, Volunteer and Professional Agreement)

#### 2. Personnel

- a. Each region must train and utilize appropriate staff to meet the needs of the mass vaccination clinics. (See Appendix K-Job Action Sheets and Appendix L, Sample Computer Programs to Assist with Mass Vaccination Clinic Staffing)
- b. Job Action Sheets must be provided to all mass vaccination clinic staff (DHEC and volunteer).

- c. Security (internal and external) and traffic flow personnel will be supplied per regional Strategic National Stockpile (SNS) plan.
- d. Public health regional immunization program manager will ensure that each mass influenza immunization clinic manager maintains a personnel roster as well as appropriate Job Action Sheets of all clinic staff and volunteers (see *Appendix N, Mass vaccination clinic Roster*).
- e. All medical screeners must be licensed MDs or APRNs. All mass vaccination clinics must include medical screener(s).
- f. All vaccine administrators must be licensed medical professionals with appropriate training.

#### 3. Facility

- a. Facilities must be arranged to ensure confidentiality and accommodate for the following stations and/or tasks (See Appendix M CDC Model for High Volume Influenza Vaccination Clinic):
  - Prescreening assess for potential exposure/infection and direct to appropriate location.
  - Medical Screening- assess/confirm priority status and direct to appropriate location.
    - Clients presenting <u>with</u> completed Pandemic Influenza Vaccination form do not need additional medical risk screening.
    - Clients presenting <u>without</u> completed Pandemic Influenza Vaccination form must have medical risk screening.
  - Education provide vaccine information statement (VIS) and other appropriate information to potential vaccinees.
  - Immunization screening –assess for contraindications; complete appropriate documentation.
  - Vaccine administration vaccinate per standing order; complete appropriate documentation.
  - Post-vaccination provide individual counseling regarding potential vaccine reactions; requirements for second vaccination, if necessary; and appropriate post-vaccination information.

- 4. Pandemic influenza vaccination education:
  - a. Clinic Greeter in a Mass Clinic or Private Provider will provide appropriate education to all potential vaccinees. The minimum educational requirements are:
    - i. Pandemic influenza fact sheet [insert hyperlink]
    - ii. Pandemic influenza Vaccine Information Statement (VIS) [insert hyperlink]
    - iii. Informed consent form for IND vaccine [insert hyperlink]
  - b. Educational resources may be obtained from DHEC Materials Library or other appropriate entities.
- 5. Refer to the <u>Immunization Documentation Policy and Procedure</u> in the Health Services Policy Manual for required documentation.
  - a. All pandemic influenza vaccine doses must be documented on the Pandemic Influenza Vaccination Form, Appendix E.
  - b. DHEC Pandemic Influenza Vaccination form will be in triplicate: pink copy for the client, white copy for the medical home and yellow copy for DHEC. The client will be provided the pink copy following vaccine administration. In the event two doses are required, the client will receive the appropriate pink copy from the perforated form after each dose.
  - c. DHEC copy will be sent to DHEC Public Health Region's Immunization Program Manager or designee to be put into appropriate database.
  - d. Information will be entered into regional database daily and batch filed as a medical record in accordance with DHEC policy.
  - e. An Excel spreadsheet should be utilized to track clients in each risk criteria category. This will allow for ease of recall when a risk group becomes eligible to receive second dose of vaccine, if applicable.
  - f. Information will be electronically sent to the DHEC Immunization Division's Database Administrator daily.
  - g. DHEC Immunization Division's Database Administrator will merge all information into one SC Statewide Pandemic Influenza database daily.
- 6. Pandemic Influenza Vaccine Adverse Event Monitoring and Response (VAERS):
  - a. The VAERS will be used to report all adverse events.

- c. All VAERS reports will be reviewed and processed by the Regional Medical Director or physician designee in a timely manner.
- d. DHEC Immunization Division will provide VAERS training to all personnel involved in adverse event monitoring and reporting (see Appendix F VAERS Training Module).
- e. Designated trained staff in each public health region will conduct passive surveillance for adverse events following pandemic influenza vaccination.
- f. For Non-IND vaccine, clinically significant adverse events and unexpected reactions for non-IND influenza vaccines should be reported through VAERS. All reports will be entered into VAERS by the public health regional staff and will be reviewed by a DHEC central office medical consultant (VAERS policy)
- g. For IND vaccine, clinically significant adverse events and unexpected reactions for IND influenza vaccines should be reported through designated mechanism (to be determined by each specific IND vaccine). All reports will be entered into a specified database by the public health regional staff and will be reviewed by a DHEC central office medical consultant.
- h. Staff trained in VAERS will facilitate and coordinate management of adverse events. Procedures for non-IND and IND vaccines will be specified.

#### 7. Components of Mass Vaccination Clinic(s)

- a. All personnel should wear appropriate identification that is visible at all times.
- b. All personnel with any potential contact with vaccinees must have received the pandemic influenza vaccine, per CDC guidance, prior to providing services in the mass vaccination clinic.
- c. During the pandemic phase, screening of potential vaccinees for infection/exposure to pandemic influenza must occur prior to entry into a vaccination clinic(s) to prevent spread of pandemic influenza.
- d. Required records will be maintained on all individuals presenting for vaccination.
- e. Job Action Sheets must be outlined in each DHEC Public Health Region's Mass Casualty Response Plan. (See Appendix K *Job Action Sheets*)
- f. All personnel participating in mass vaccination clinics will receive appropriate training.

#### References:

Health and Human Services Pandemic Influenza Plan <a href="http://www.hhs.gov/pandemicflu/plan/">http://www.hhs.gov/pandemicflu/plan/</a>

DHEC Immunization Documentation Policy <a href="http://dhecnet/health\_serv/policy/immun.htm">http://dhecnet/health\_serv/policy/immun.htm</a>

DHEC Regional Strategic National Stockpile Plans – access via Regional Public Health Preparedness Directors or designee

### Appendices

| Appendix A   | HHS Vaccine Priority Group Recommendations                                      |
|--------------|---|
| Appendix B   | MOA for Pandemic Influenza Mass Vaccination Facilities                          |
| Appendix C-1 | MOA for DHEC Pandemic Influenza Mass Vaccination Clinic Vaccine Providers/Staff |
| Appendix C-2 | Volunteer Health Professional Agreement (DHEC 886)                              |
| Appendix D   | MOA for Private Pandemic Influenza Vaccine Providers                            |
| Appendix E   | Pandemic Influenza Vaccination Form   |
| Appendix F   | VAERS Training Module   |
| Appendix G   | VAERS Reporting Form and Instructions   |
| Appendix H   | Pandemic Influenza Vaccine Chain of Custody/Temperature<br>Monitoring Form      |
| Appendix I   | Pandemic Influenza Order Form/Instructions                                      |
| Appendix J   | Pandemic Influenza Vaccine Temperature Log/Instructions                         |
| Appendix K   | Job Action Sheets   |
| Appendix L   | Sample Computer Programs to Assist with Mass Vaccination Clinic Staffing        |
| Appendix M   | CDC High-Volume Influenza Vaccination Clinic                                    |
| Appendix N-1 | Mass Vaccination Clinic Roster (Licensed Personnel)                             |
| Appendix N-2 | Mass Vaccination Clinic Roster (Non-licensed Personnel)                         |
|              |   |

#### Appendix A – HHS Vaccine Priority Group Recommendations

#### Tier 1 Subtier A

- Vaccine and antiviral manufacturers and others essential to manufacturing and critical support
- Medical workers and public health workers who are involved in direct client contact, other support services essential for direct client care, and vaccinators (this is inclusive of federal healthcare providers to Indian nations and tribes).

#### Rationale:

- Need to assure maximum production of vaccine and antiviral drugs
- Healthcare workers are required for quality medical care (studies show outcome is associated with staff-to-client ratios). There is little surge capacity among healthcare sector personnel to meet increased demand.

#### Subtier B

- Persons <u>></u> 65 years with one or more influenza high-risk conditions, not including essential hypertension.
- Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertention.
- Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year

#### Rationale:

o These groups are at high risk of hospitalization and death. Excludes elderly in nursing homes and those who are immunocompromised and would not likely be protected by vaccination.

#### Subtier C

- Pregnant women
- Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine
- Household contacts of children < 6 months old</li>

#### Rationale:

- In past pandemics and for annual influenza, pregnant women have been at high risk; vaccination will also protect the infant who cannot receive vaccine
- Vaccination of household contacts of immunocompromised and young infants will decrease risk of exposure and infections among those who cannot be directly protected by vaccination.

#### Subtier D

- Public health emergency response workers critical to pandemic response
- Key government leaders

#### Rationale:

- o Critical to implement pandemic response such as providing vaccinations and managing/monitoring response activities.
- o Preserving decision-making capacity also critical for managing and implementing a response.

#### Tier 2

#### Subtier A

- Healthy 65 years and older
- 6 months to 64 years with one high-risk condition
- 6-23 months old, healthy

#### Rationale:

 Groups that are also at increased risk but not as high risk as population in Tier 1B

#### Subtier B

- Other public health emergency responders
- Public safety workers including police, fire, 911 dispatchers, and correctional facility staff
- Utility workers essential for maintenance of power, water, and sewage system functioning
- Transportation workers transporting fuel, water, food, and medical supplies as well as public ground transportation
- Telecommunications/IT for essential network operations and maintenance

#### Rationale:

 Includes critical infrastructure groups that have impact on maintaining health (e.g. public safety or transportation of medical supplies and food); implementing a pandemic response; and on maintaining societal functions

#### Tier 3

- Other key government health decision-makers
- Funeral directors/embalmers

#### Rationale:

 Other important societal groups for a pandemic response but of lower priority

#### Tier 4

- Healthy persons 2-64 years not included in above categories Rationale:
  - All persons not included in other groups based on objective to vaccinate all those who want protection

#### Appendix B – MOA for Pandemic Influenza Mass Vaccination Facilities

#### MEMORANDUM OF AGREEMENT

#### BFTWFFN

# SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL (REGION NAME )

#### AND

#### (NAME OF CONTRACTING PARTY)

I. PURPOSE: ADMINISTRATION OF PANDEMIC INFLUENZA VACCINE

To effectively respond to a Pandemic Influenza event that may effect the citizens of South Carolina, the South Carolina Department of Health and Environmental Control (hereafter referred to as DHEC) and (Name of Contracting Party) (hereafter referred to as \_\_\_\_\_\_\_) hereby enter into this Memorandum of Agreement (hereafter MOA) for the purpose of providing location(s) for use as a mass vaccination site during a declared state of emergency.

#### II. SCOPE OF SERVICES:

- A. Responsibilities of DHEC. Under the terms of this MOA, and in the event that the Governor or his designee has issued an agency directive for mass immunization, DHEC shall be responsible for the following activities during the state of emergency.
  - 1. Provide adequate personnel to sustain operations of the mass vaccination clinic for the duration of the declared emergency.
  - 2. Provide adequate supplies and materials to sustain operations of the mass vaccination clinic for the duration of the declared emergency.
  - 3. Ensure adequate security for the mass vaccination clinic for the duration of the declared emergency.
  - 4. Provide adequate planning and coordination to sustain mass vaccination clinic for the duration of the declared emergency.

- 5. Ensure adequate traffic control for the mass vaccination clinic for the duration of the declared emergency.
- B. Responsibilities of (Contracting Party). Under the terms of this MOA and in the event that the Governor or his designee has declared a state of emergency, (Contracting Party) shall be responsible for the following activities during the state of emergency.
  - 1. Provide the use of (list name of facility) located at (list address here) for use as a mass vaccination clinic site for the duration of the declared state of emergency.
  - 2. Provide DHEC with 24-hour contact information for two individuals who can provide access to the identified facility and can be at the site within 12 hours of notification.
  - 3. Permit DHEC to remain, occupy and utilize the site until the state of emergency is no longer in effect.
  - 4. Provide appropriate controlled cold storage device (e.g. refrigeration with temperature monitoring) per DHEC Storage and Handling guidelines and provide back-up generator power, as needed.
  - 5. Permit DHEC to enter and inspect the site at reasonable times to determine its suitability for use as a mass vaccination clinic and for the purposes of logistical planning.

#### III. TERMS AND CONDITIONS:

Effective Dates.

both parties.

This MOA shall be effective on \_\_[date]\_\_\_ or when all parties have signed, whichever is later, and will terminate on \_\_\_\_[date]\_\_\_\_. This MOA is renewable for three additional one year periods based on an annual review of criteria listed under Evaluation of MOA and agreement by

B. Termination.

Α.

- 1. Subject to the provisions contained below, this MOA may be terminated by either party providing thirty (30) days advance written notice of termination.
- 2. DHEC may terminate this MOA for cause, default or negligence on the part of (the Contracting Party) at any time without thirty days advance written notice.

#### C. Amendment.

Any changes to this MOA, which are mutually agreed upon between DHEC and (the Contracting Party), shall be incorporated in written amendment to this MOA and will not become effective until the amendment is signed by all parties.

#### D. Nondisclosure

To the extent permitted by law, the parties agree that neither will disclose the location of the drug distribution warehouse site or dispensing site or the nature of this effort except as is necessary to fulfill its mission, and statutory and regulatory responsibilities.

#### E. Records

DHEC will maintain records it generates at the Dispensing Site for 6-years pursuant to the agency records retention policy. These records will be maintained at the location listed on the Pharmacy permit.

#### F. Liability.

Neither party shall be liable for any claims, demands, expenses, liabilities and losses (including reasonable attorney's fees) which may arise out of any acts or failures to act by the other party, its employee or agents, in connection with the performance of services pursuant to this MOA.

#### G. Non-Discrimination.

No person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this MOA on the grounds of race,

handicap, color, sex, religion, age, health status or national origin.

#### H. Controlled Substance Statement.

The (Contracting Party) certifies that he/she will not engage in the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance in the performance of this MOA.

#### I. Evaluation of MOA.

Appropriate staff of (the Contracting Party) and DHEC will meet annually to evaluate this MOA based on the responsibilities for each party listed under section II, Scope of Services, of this agreement.

#### J. Governing Law.

This MOA shall be construed and enforced in accordance with appropriate federal law and the laws of the State of South Carolina. All disputes, claims or controversies relating to the agreement shall be subject to the jurisdiction and process of the courts of the State of South Carolina.

#### K. Insurance.

Each of the parties agrees to maintain professional, malpractice and general liability insurance, and may be required to provide the other party with satisfactory evidence of such coverage. Neither party will provide coverage for the other party's employees. Each party shall be responsible for coverage of its respective employees.

#### L. Expenses

Each party shall bear and be responsible solely for its own costs and expenses necessary to comply with this MOA.

#### M. Severability.

Should a court of competent jurisdiction rule any portion of this agreement invalid, null, or void, that fact shall not affect or invalidate any other portion or section of the agreement and all

remaining portions and sections of the agreement remain in full force and effect.

| AS TO DHEC  | AS TO THE CONTRACTING PARTY     |
|---|---------------------------------|
| BY:<br>(REGIONAL HEALTH DIRECTOR<br>OR REGIONAL MEDICAL DIRECTO<br>ADDRESS: |                                 |
| PHONE NUMBER: DATE:   |                                 |
| MAILING ADDRESS:  |                                 |
| THIS AGREEMENT IS NOT OFFICIAL A CHIEF OF STAFF.                            | AND BINDING UNTIL SIGNED BY THE |
| (Chief of Staff, DHEC)  |                                 |
| DATE:   |                                 |

## Appendix C -1 – MOA for DHEC Pandemic Influenza Mass Vaccination Clinic Vaccine Providers

#### MEMORANDUM OF AGREEMENT

#### **BETWEEN**

# SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL (DHEC) (REGION NAME)

**AND** 

(NAME OF CONTRACTING PARTY—Pandemic Influenza Mass Vaccination Clinic Vaccine Volunteer Providers)

| l. | PURPOSE | : |
|----|---------|---|
|    |         |   |

| The South                 | n Car | olina De | epartm | ent of F | łealtl | h and E  | invironme | ental Co | ntrol |
|---------------------------|-------|----------|--------|----------|--------|----------|-----------|----------|-------|
| (hereafter                | refe  | erred to | as     |          |        |          |           | )        | and   |
| (Name                     | of    | Contrac  | ting   | Party)   | (he    | ereafter | referre   | ed to    | as    |
|                           |       |          |        |          | )      | hereby   | enter     | into     | this  |
| Memorano                  | dum   | of Agr   | eemen  | t (herea | after  | MOA)     | for the   | purpos   | e of  |
| identifying<br>Clinic(s). | g sta | aff for  | DHEC   | Pander   | nic    | Influenz | a Mass    | Vaccin   | ation |

#### II. SCOPE OF SERVICES:

- A. Responsibilities of the *DHEC Public Health Region*: Under the terms of this MOA, the *DHEC Public Health Region* shall be responsible for:
  - 1. Following the "Pandemic Influenza Mass Vaccination Policy and Procedure" which is based on the Department of Health and Human Services (HHS) guidance.
  - 2. Following the DHEC Immunization Division's guidelines for distribution of vaccine.
  - 3. Pandemic influenza data entry.
  - 4. Providing training and consultation to volunteer staff regarding pandemic vaccine concerns/issues.
  - 5. Verification of licensure status
  - 6. Providing supervision for volunteer staff
  - 7. Assuring volunteer staff have appropriate identification

- B. Responsibilities of Pandemic Influenza Mass Vaccination Clinic Vaccine Volunteer Providers/Staff:
  - Under the terms of this MOA, Pandemic Influenza Mass Vaccination Clinic Vaccine Volunteer Providers/Staff shall be responsible for:
    - 1. Providing documentation to validate they have been vaccinated with the pandemic influenza vaccine at least 2 weeks prior to providing services in the mass vaccination clinic.
    - 2. Administering vaccine in accordance with DHEC Pandemic Influenza Mass Vaccination Policy and Procedure and the DHEC Pandemic Influenza Vaccine Standing Order.
    - 3. Consulting with the DHEC Public Health Region's Immunization Program Manager or designee for any questions or concerns.
    - 4. Participating in appropriate training for pandemic influenza mass vaccination services.
    - 5. Following duties outlined in the job actions sheets based on assigned position.
    - 6. Providing documentation of current licensure to DHEC public health regional staff.

#### III. TERMS AND CONDITIONS:

A. Effective Dates.

| This MOA shall be effective on               | or when al        |
|--|-------------------|
| parties have signed, whichever is later, and | will terminate or |
| (NOTE: If the MOA is su                      | bject to renewal, |
| then include language such as "This MOA      | is renewable for  |
| four additional one year periods based on an | annual review of  |
| criteria listed under Evaluation of MOA an   | d agreement by    |
| both parties)                                |                   |

- B. Termination.
  - 1. Subject to the provisions contained below, this MOA may be terminated by either party providing thirty (30) days advance written notice of termination.
  - 2. Funding to support performance of this MOA may be payable from State and/or Federal and/or other appropriations. In the event sufficient appropriations are

not made to support performance under this MOA, it shall terminate without further obligations of the parties except as set forth herein.

3. DHEC may terminate this MOA for cause, default or negligence on the part of (the Contracting Party) at any time without thirty days advance written notice.

#### C. Amendment.

Any changes to this MOA, which are mutually agreed upon between DHEC and (the Contracting Party), shall be incorporated in written amendment to this MOA and will not become effective until the amendment is signed by each party.

#### D. Confidentiality.

The Contractor agrees to abide by DHEC's policy of confidentiality, which states that all information as to personal facts and circumstances given or made available to employees/volunteers and/or contractors of DHEC in administration of programs shall be held confidential and shall not be divulged without consent of the programs and services and individual(s) to which it pertains. Confidential agency information and action shall not be divulged.

Certain information received by DHEC may not be released pursuant to the Family Privacy Protection Act. Information that is otherwise available to the public under the Freedom of Information Act may be released in accordance with State law. Should information identify a DHEC client or employee, it may not be released outside of the agency except upon receipt of a properly completed authorization signed by the individual or his/her parent or guardian. If information is released pursuant to the receipt of a properly completed authorization, documentation of the release must be maintained. A copy of the authorization must be included in this documentation.

Protected Health Information generally cannot be released except pursuant to a proper authorization by the client or his/her parent or guardian, or pursuant to a specific exception under the Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164). DHEC may conduct routine audits of health records to ensure compliance with this procedure.

Any unauthorized disclosure of confidential information may result in termination of this contractual relationship with DHEC and may be grounds for fines, penalties, imprisonment, civil suit, or debarment from doing business with the State.

The Contracting Party shall immediately notify the Regional Medical Director and DHEC HIPAA Privacy Officer of any possible breach of privacy or security of DHEC client's protected health information under the HIPAA Privacy Rule or applicable state law that occurs in the course of performing this Agreement.

The Contracting Party and employees/agents of the Contracting Party will be required to sign DHEC's Confidentiality Agreement (DHEC form #0321), a copy of which is attached hereto. Alternatively, if the Contracting Party desires to rely upon an Confidentiality Agreement signed employees/agents, a copy of the Confidentiality Agreement must first be provided to the DHEC Contract Officer for evaluation, and the Contracting Party must provide verification that employee/agents obtaining access to DHEC confidential information in the course of performing this agreement have executed the Confidentiality Agreement.

#### E. Records.

Records with respect to all matters covered by this MOA must be retained for 6-years after the end of the period of this MOA and shall be available for audit and inspection at any time such audit is deemed necessary by DHEC. If audit has begun but is not completed at the end of the 6-year period, the records shall be retained until resolution of the audit findings.

#### F. Liability.

Neither party shall be liable for any claims, demands, expenses, liabilities and losses (including reasonable attorney's fees) which may arise out of any acts or failures to act by the other party, its employee or agents, in connection with the performance of services pursuant to this MOA.

#### G. Non-Discrimination.

No person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this MOA on the grounds of race, handicap, color, sex, religion, age, health status or national origin.

#### H. Controlled Substance Statement.

The (Contracting Party) certifies that he/she will not engage in the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance in the performance of this MOA.

#### I. Evaluation of MOA. [If applicable].

Appropriate staff of (the Contracting Party) and DHEC will meet on a regular basis [may specify time, place and number of meetings] to evaluate this MOA based on the following perspectives and indicators:\_\_\_\_\_\_\_.

#### J. Governing Law.

The agreement and any dispute, claim, or controversy related to the agreement shall, in all respects, be interpreted, construed, enforced and covered by and under the laws of the state of South Carolina. All disputes, claims or controversies relating to the agreement shall be resolved in accordance with the South Carolina Procurement Code, Section 11-35-10, et. Seg., and the contractor agrees to subject himself to the jurisdiction and process of the courts of the State of South Carolina

#### K. Insurance. [If applicable]

Each of the parties agree to maintain professional, malpractice and general liability insurance, and may be required to provide the other party with satisfactory evidence of such coverage. Neither party will provide individual coverage for the other party's employees and each party shall be responsible for coverage of its respective employees.

#### L. Licenses. [If applicable]

The parties agree that during the term of this MOA, each party shall maintain its respective federal and state licenses,

- certifications, and accreditations required for the provision of services herein.
- M. Each party shall bear and be responsible solely for its own costs and expenses necessary to comply with this MOA.
- HIPAA Training. [If applicable] N. Prior to participating in any DHEC clinical activity or rendering any service to DHEC under this Agreement, the Contracting Party and employee/agents of the Contracting Party will be educated and trained regarding the Health Insurance Portability and Accountability Act of 1996 and related Regulations pertaining to the privacy and security of protected health information (the HIPAA Privacy Rule.) The Contracting Party will provide documentation of successful completion of this training to the Contract Officer prior to initiating performance of this If this training has not been conducted, or Agreement. documentation of training has not been provided, the Contracting Party and its employees/agents will be required to view DHEC's HIPAA training video(s) and receive necessary instruction on the DHEC forms referenced in the training prior to initiating performance of this Agreement.

| PARTY   |           |
|---|-----------|
| BY:<br>(REGIONAL HEALTH DIRECTOR OR<br>REGIONAL MEDICAL DIRECTOR) | BY:(NAME) |
| DATE:   | DATE:     |
| MAILING ADDRESS: _  |           |
| THIS AGREEMENT IS NOT OFFICIAL AND ESTAFF.                        |           |
| (Chief of Staff, DHEC)  |           |
| DATE:   | <u> </u>  |

AS TO DHEC

AS TO THE CONTRACTING

Appendix C -2 – Volunteer Health Professional Agreement for DHEC Pandemic Influenza Mass Vaccination Clinic



# VOLUNTEER HEALTH PROFESSIONAL AGREEMENT for PANDEMIC INFLUNENZA BETWEEN SC DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL and

| (Print Name of Provider) |  |
|--------------------------|--|

The undersigned agrees to provide volunteer services for the SC Department of Health and Environmental Control (DHEC) as described below, and DHEC appoints the undersigned as a volunteer under the Government Volunteers Act, S.C. Code Sections 8-25-10 to -50, and the Emergency Health Powers Act, S.C. Code Sections 44-4-100 to -570, as applicable.

- I. SCOPE OF SERVICES: Provide volunteer \_\_\_\_\_\_ (medical, nursing, pharmaceutical, etc.) services for and under the direction of DHEC during the period of public health emergency, such public health emergency having been declared by [the Governor] **OR** [the DHEC Commissioner] on \_\_\_\_[DATE]\_\_\_\_\_.
  - A. Responsibilities of the *DHEC Public Health Region*:
    Under the terms of this Volunteer Agreement, the *DHEC Public Health Region* shall be responsible for:
    - 1. Following the "Pandemic Influenza Mass Vaccination Policy and Procedure" which is based on the Department of Health and Human Services (HHS) guidance.
    - 2. Following the DHEC Immunization Division's guidelines for distribution of vaccine.
    - 3. Pandemic influenza data entry.
    - 4. Providing training and consultation to volunteer staff regarding pandemic vaccine concerns/issues.
    - 5. Verification of licensure status
    - 6. Providing supervision for volunteer staff

- 7. Assuring volunteer staff have appropriate identification
- B. Responsibilities of Pandemic Influenza Mass Vaccination Clinic Vaccine Volunteer DHEC Providers/Staff:
  Under the terms of this Volunteer Agreement, Pandemic Influenza Mass Vaccination Clinic Vaccine Volunteer DHEC Providers/Staff shall be responsible for:
  - 1. Providing documentation to validate they have been vaccinated with the pandemic influenza vaccine at least 2 weeks prior to providing services in the mass vaccination clinic.
  - 2. Administering vaccine in accordance with DHEC Pandemic Influenza Mass Vaccination Policy and Procedure and the DHEC Pandemic Influenza Vaccine Standing Order.
  - 3. Consulting with the DHEC Public Health Region's Immunization Program Manager or designee for any questions or concerns.
  - 4. Participating in appropriate training for pandemic influenza mass vaccination services.
  - 5. Following duties outlined in the job actions sheets based on assigned position.
  - 6. Providing documentation of current licensure to DHEC public health regional staff.

#### II. TIME OF PERFORMANCE:

This agreement shall be effective for the period of public health emergency and as long as necessary to continue to provide care and treatment for victims of the public health emergency.

#### III. TERMS AND CONDITIONS:

- A. Either party may terminate this agreement by giving written notice, or at such time that the public health emergency no longer exists and health care is not needed for these purposes.
- B. All services shall be rendered within the scope and limitations of applicable DHEC regulations.
- C. The volunteer agrees to abide by DHEC's policy of confidentiality and shall read and sign the DHEC Confidentiality Agreement

- (DHEC 0321) before they become involved in the administration of any program and/or service with DHEC.
- D. No person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this agreement on the grounds of handicap disability, age, health status, race, color, sex, religion or national origin.
- E. The volunteer certifies that he/she will not engage in the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance in the performance of this agreement.
- F. If the volunteer is an in-state health care provider, the volunteer shall be currently licensed/accredited in the State of South Carolina by the recognized licensing authority over his/her profession. Such licensure shall be maintained at the volunteer's expense for the entire length of this agreement and failure to maintain such licensure will void this agreement. In addition, if continuing professional education is a requirement of licensure then such educational requirements must be maintained at the volunteer's expense.
- G. If the volunteer is an out-of-state health care provider, the volunteer shall be currently licensed/accredited in his/her state of residence by the recognized licensing authority over his/her profession. Such licensure shall be maintained at the volunteer's expense for the entire length of this agreement and failure to maintain such licensure will void this agreement. In addition, if continuing professional education is a requirement of licensure then such educational requirements must be maintained at the volunteer's expense.
- H. DHEC provides liability coverage to volunteers while they are exclusively acting on behalf of DHEC and within their scope as a volunteer with DHEC. This coverage is provided in accordance with DHEC's automobile liability policy, tort liability policy, and professional liability policy, and in accordance with and the Government Volunteers Act, S.C. Code Section 8-25-10, et seq., and the Emergency Health Powers Act, S.C. Code Section 44-4-100, et seq., as applicable. Acts of gross negligence or willful misconduct are specifically excluded from liability coverage. DHEC does not provide individual medical malpractice coverage

DHEC/Immz Div/PanFlu

- or other insurance coverage to any physician or other volunteer for services outside the scope of his/her volunteer activity.
- I. Volunteers are not employees of DHEC and are therefore not covered by Workmen's Compensation Insurance.
- J. Volunteers must follow DHEC policies and procedures and medical standing orders issued during the public health emergency under the ESF-8 Unified Medical Command or otherwise. Failure to follow DHEC policies and procedures and medical standing orders issued during the public health emergency could result in termination of the service agreement or the loss of the applicable civil liability protections or both.

| AS TO DHEC | AS TO VOLUNTEER  |
|------------|------------------|
| BY:(DHEC)  | BY:(VOLUNTEER)   |
|            | LICENSE NUMBER:  |
|            | DEA NUMBER:      |
|            | EXPIRATION DATE: |
| LOCATION:  |                  |
|            | MAILING ADDRESS: |
|            |                  |
|            |                  |
| DATE:      | DATE:            |

#### Appendix D – MOA for Private Pandemic Influenza Vaccine Providers

#### MEMORANDUM OF AGREEMENT

#### **BETWEEN**

# SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL (DHEC) (REGION NAME)

**AND** 

(NAME OF CONTRACTING PARTY—Private Pandemic Influenza Vaccine Providers)

| I  | DI I | IDD     | OS                       | F٠ |
|----|------|---------|--------------------------|----|
| Ι. |      | , 1 🗸 1 | $\mathcal{O}\mathcal{O}$ | ┖. |

| The Sou   | th Ca  | arolina Departr | ment of H | Health and En | vironment | al Co  | ntrol |
|-----------|--------|-----------------|-----------|---------------|-----------|--------|-------|
| (hereafte | er ref | erred to as _   |           |               |           | )      | and   |
| (Name     | of     | Contracting     | Party)    | (hereafter    | referred  | to     | as    |
|           |        | _               |           | ) hereby      | enter     | into   | this  |
| Memorai   | ndum   | of Agreeme      | nt (herea | after MOA) f  | or the p  | urpose | e of  |
| providing | g Par  | ndemic Influer  | nza vacci | ne for Privat | e Provide | r Vac  | cine  |
| distribut | ion ar | nd administrati | on.       |               |           |        |       |

#### II. SCOPE OF SERVICES:

- A. Responsibilities of the *DHEC Public Health Region*:
  Under the terms of this MOA, the *DHEC Public Health Region* shall be responsible for:
  - 1. Providing Pandemic Influenza vaccine when available.
  - 2. Following the "Pandemic Influenza Mass Vaccination Policy and Procedure" which is based on the Department of Health and Human Services (HHS) guidance.
  - 3. Following the DHEC Immunization Division's guidelines for distribution of vaccine.
  - 4. Pandemic influenza data entry.
  - 5. Providing consultation to the private pandemic influenza vaccine providers regarding pandemic vaccine concerns/issues.
- B. Responsibilities of *Private Pandemic Influenza Vaccine Provider*:

Under the terms of this MOA, *Private Pandemic Influenza Vaccine Provider* shall be responsible for:

- 1. Administering vaccine in accordance with the Department of Health and Human Services (HHS) Priority Groups.
- 2. Utilizing proper acquisition, storage, safeguarding, cold-chain management and disposal procedures for vaccine according to DHEC guidelines [hyperlink].
- 3. Administering the vaccine per manufacturer's package insert.
- Reporting adverse events related to vaccine administration through the Vaccine Adverse Events Reporting System (VAERS). (See Appendix B for VAERS Reporting Guidelines.)
- 5. Submitting the completed DHEC Pandemic Influenza Vaccination Form to the DHEC Public Health Region's Immunization Program Manager or designee on a daily basis. This is required to expedite reporting of vaccine usage, etc to appropriate federal entities.
- 6. Consulting with the DHEC Public Health Region's Immunization Program Manager or designee for any questions or concerns.
- 7. Responsible for following vaccine inventory guidelines.
- 8. Maintaining adequate supply inventory for vaccine administration.
- 9. Responsible for vaccine security upon receipt.

#### III. TERMS AND CONDITIONS:

Effective Dates.

| This MOA shall be effective on                       | or when al   |
|--|--------------|
| parties have signed, whichever is later, and will to | erminate or  |
| (NOTE: If the MOA is subject                         | to renewal   |
| then include language such as "This MOA is rer       | newable for  |
| four additional one year periods based on an annu    | al review of |
| criteria listed under Evaluation of MOA and agr      | eement by    |
| both parties)  | _            |

B. Termination.

Α.

- 1. Subject to the provisions contained below, this MOA may be terminated by either party providing thirty (30) days advance written notice of termination.
- 2. Funding to support performance of this MOA may be payable from State and/or Federal and/or other appropriations. In the event sufficient appropriations are not made to support performance under this MOA, it shall terminate without further obligations of the parties except as set forth herein.
- 3. DHEC may terminate this MOA for cause, default or negligence on the part of (the Contracting Party) at any time without thirty days advance written notice.

#### C. Amendment.

Any changes to this MOA, which are mutually agreed upon between DHEC and (the Contracting Party), shall be incorporated in written amendment to this MOA and will not become effective until the amendment is signed by each party.

#### D. Confidentiality.

DHEC/Immz Div/PanFlu

The Contractor agrees to abide by DHEC's policy of confidentiality, which states that all information as to personal facts and circumstances given or made available to employees/volunteers and/or contractors of DHEC in administration of programs shall be held confidential and shall not be divulged without consent of the programs and services and individual(s) to which it pertains. Confidential agency information and action shall not be divulged.

Certain information received by DHEC may not be released pursuant to the Family Privacy Protection Act. Information that is otherwise available to the public under the Freedom of Information Act may be released in accordance with State law. Should information identify a DHEC client or employee, it may not be released outside of the agency except upon receipt of a properly completed authorization signed by the individual or his/her parent or guardian. If information is released pursuant to the receipt of a properly completed authorization, documentation of the release must be maintained. A copy of the authorization must be included in this documentation.

Protected Health Information generally cannot be released except pursuant to a proper authorization by the client or his/her parent or guardian, or pursuant to a specific exception under the Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164). DHEC may conduct routine audits of health records to ensure compliance with this procedure.

Any unauthorized disclosure of confidential information may result in termination of this contractual relationship with DHEC and may be grounds for fines, penalties, imprisonment, civil suit, or debarment from doing business with the State.

The Contracting Party shall immediately notify the Regional Medical Director and DHEC HIPAA Privacy Officer of any possible breach of privacy or security of DHEC client's protected health information under the HIPAA Privacy Rule or applicable state law that occurs in the course of performing this Agreement.

The Contracting Party and employees/agents of the Contracting Party will be required to sign DHEC's Confidentiality Agreement (DHEC form #0321), a copy of which is attached hereto. Alternatively, if the Contracting Party desires to rely upon an Agreement Confidentiality signed employees/agents, a copy of the Confidentiality Agreement must first be provided to the DHEC Contract Officer for evaluation, and the Contracting Party must provide verification that obtaining employee/agents access to DHEC confidential information in the course of performing this agreement have executed the Confidentiality Agreement.

#### E. Records.

Records with respect to all matters covered by this MOA must be retained for 6-years after the end of the period of this MOA and shall be available for audit and inspection at any time such audit is deemed necessary by DHEC. If audit has begun but is not completed at the end of the 6-year period, the records shall be retained until resolution of the audit findings.

#### F. Liability.

Neither party shall be liable for any claims, demands, expenses, liabilities and losses (including reasonable attorney's fees) which

may arise out of any acts or failures to act by the other party, its employee or agents, in connection with the performance of services pursuant to this MOA.

### G. Non-Discrimination.

No person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this MOA on the grounds of race, handicap, color, sex, religion, age, health status or national origin.

#### H. Controlled Substance Statement.

The (Contracting Party) certifies that he/she will not engage in the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance in the performance of this MOA.

## I. Evaluation of MOA. [If applicable].

Appropriate staff of (the Contracting Party) and DHEC will meet on a regular basis [may specify time, place and number of meetings] to evaluate this MOA based on the following perspectives and indicators:\_\_\_\_\_\_\_.

## J. Governing Law.

The agreement and any dispute, claim, or controversy related to the agreement shall, in all respects, be interpreted, construed, enforced and covered by and under the laws of the state of South Carolina. All disputes, claims or controversies relating to the agreement shall be resolved in accordance with the South Carolina Procurement Code, Section 11-35-10, et. Seg., and the contractor agrees to subject himself to the jurisdiction and process of the courts of the State of South Carolina

## K. Insurance. [If applicable]

Each of the parties agree to maintain professional, malpractice and general liability insurance, and may be required to provide the other party with satisfactory evidence of such coverage. Neither party will provide individual coverage for the other party's employees and each party shall be responsible for coverage of its respective employees.

## L. Licenses. [If applicable]

The parties agree that during the term of this MOA, each party shall maintain its respective federal and state licenses, certifications, and accreditations required for the provision of services herein.

- M. Each party shall bear and be responsible solely for its own costs and expenses necessary to comply with this MOA.
- N. HIPAA Training. [If applicable]

Prior to participating in any DHEC clinical activity or rendering any service to DHEC under this Agreement, the Contracting Party and employee/agents of the Contracting Party will be educated and trained regarding the Health Insurance Portability and Accountability Act of 1996 and related Regulations pertaining to the privacy and security of protected health information (the HIPAA Privacy Rule.) The Contracting Party will provide documentation of successful completion of this training to the Contract Officer prior to initiating performance of this If this training has not been conducted, or provided. documentation of training has not been Contracting Party and its employees/agents will be required to view DHEC's HIPAA training video(s) and receive necessary instruction on the DHEC forms referenced in the training prior to initiating performance of this Agreement.

| PARTY   | AS TO THE CONTRACTING |
|---|-----------------------|
| BY:<br>(REGIONAL HEALTH DIRECTOR OR<br>REGIONAL MEDICAL DIRECTOR) | BY:(NAME)             |
| DATE:   | DATE:                 |
| MAILING ADDRESS:  |                       |
| VACCINE SHIPPING ADDRESS:   |                       |

. . . . . . . . . . .

| VAFAC PIN # (IF VAFAC PROVIDER):   |
|--|
| THIS AGREEMENT IS NOT OFFICIAL AND BINDING UNTIL SIGNED BY THE CHIEF OF STAFF. |
| (Chief of Staff, DHEC)   |
| DATE:  |

## Appendix E – Pandemic Influenza Vaccination form

| PRO             | H E C  | Pander  | nic       | Influenza Vaccination   |
|-----------------|--|---|-----------|---|
|                 | Name:  |   | Na        | me:   |
|                 | Mailing Address:   |   | Ma        | iling Address:  |
| 0               | Phone: (Home)  |   | Ph        | one: (Home)   |
| at II           | Date of Birth:   |   | Dat       | te of Birth:  |
| Patient ID      | Age:   | Gender: □ Male □ Female   | Ag        | e: Gender:  |
| Pa              | If less than 18, Guard   | lian's Name:  | If le     | ess than 18, Guardian's Name:   |
|                 | If yes, please list me reaction:   | ny medications or eggs? □Yes □No<br>dications/food and type of allergic   |           | e you allergic to any medications or eggs?   Yes   No  No  res, please list medications/food and type of allergic reaction:   |
|                 |  | SK CRITERIA:  |           | RISK CRITERIA:  |
|                 | essential healthcar c. healthcare workers contact and essent d age ≥ 65 yrs. with 1 (not essential HTN e. age 6 mo64 yrs. v conditions (not ess f. age ≥ 6 mos. with 1 influenza, or other year g. pregnant h. household contacts persons i. household contacts public health emer pandemic response k. key government lea involved in pandem l. age 6 mos64 yrs. n. age 6 mos64 yrs. n. age 6-23 mos. and o. other public health patient care duties) | with direct patient contact and e support staff in public health with direct patient ial public health support staff one influenza high-risk condition ) with > two influenza high-risk ential HTN) nx of hospitalization for pneumonia, influenza high-risk condition in past s of severely immunocompromised s of children aged < 6 months gency response workers critical to enders and health decision-makers nic prevention and control efforts nealthy with one high-risk condition healthy emergency responders (non-direct of transportation/telecommunications/IT matth decision-makers hall the decision-makers |           | a. vaccine/antiviral manufacturer b. healthcare workers with direct patient contact and essential healthcare support staff c. healthcare workers in public health with direct patient contact and essential public health support staff d. age ≥ 65 yrs. with ≥ one influenza high-risk condition (not essential HTN) e. age 6 mo64 yrs. with ≥ two influenza high-risk conditions (not essential HTN) f. age ≥ 6 mos. with hx of hospitalization for pneumonia, influenza, or other influenza high-risk condition in past year g. pregnant h. household contacts of severely immunocompromised persons household contacts of children aged < 6 months public health emergency response workers critical to pandemic response k. key government leaders and health decision-makers involved in pandemic prevention and control efforts age ≥ 65 yrs. and healthy m. age 6 mos64 yrs. with one high-risk condition n. age 6-23 mos. and healthy other public health emergency responders (non-direct patient care duties) p. public safety/utility/transportation/telecommunications/IT workers g. key government health decision-makers f. funeral directors/embalmers s. age 2-64 yrs. and healthy |
| _               | h Risk Conditions (if app  |   | -         | h Risk Conditions (if applicable):  |
| NV<br>the<br>MD | AC/ACIP Vaccine Priorit<br>U.S. Department of Hea<br>D/APRN Signature:   | s designated above as described in the<br>y Group Recommendations published by<br>lth and Human Services Nov. 2, 2005.  | the<br>MD | rtify this patient has risks designated above as described in the AC/ACIP Vaccine Priority Group Recommendations published by U.S. Department of Health and Human Services Nov. 2, 2005. //APRN Signature:  |
| Lic             | ense #:  | - ADMINISTRATION  | Lice      | ense #:   |
|                 |  | E ADMINISTRATION  |           | VACCINE ADMINISTRATION  |
| Dose 1:         | Manufacturer Injection Site  Provider Name/Site: Provider Address: Provider Signature:   | Lot # Exp. Date   Injection Route   VIS Date  | Dose 2:   | Date Vaccine Name  Manufacturer Lot # Exp. Date  Injection Site Injection Route VIS Date  Provider Name/Site:  Provider Address:  Provider Signature:   |

DHEC 1155 (9/2006)

South Carolina Department of Health & Environmental Control

## SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL Pandemic Influenza Vaccination (Instructions for Completing)

#### **PURPOSE:**

To provide documentation of the patient's pandemic influenza risk(s) per the DHHS priority groupings; to provide documentation for vaccine administration; and to provide required reporting elements for the CDC.

#### **EXPLANATION AND DEFINITION:**

The form is to be completed when an individual presents for pandemic influenza vaccine. The form will be utilized to document risk(s), as well as document dose 1 and dose 2 of the vaccine.

Except for the Vaccine Administration portion of the form, this form may be completed and kept on file by the medical provider if the medical provider plans to be a pandemic influenza vaccination site. If the medical provider does NOT plan to be a pandemic influenza vaccination site the form may be completed, except for the Vaccination Administration portion of the form, and given to the patient who could take the form to a pandemic influenza vaccination site.

#### ITEM-BY-ITEM INSTRUCTIONS:

#### Demographic Information:

Note: The "demographic information" section should be completed by the patient/guardian.

Name: Patient/guardian enters full name.

Mailing Address: Patient/guardian enters current mailing address.

Phone: Patient/guardian enters all applicable phone numbers.

Date of Birth: Patient/guardian enters month/day/year of birth.

Age: Patient/guardian enters age in years and/or months.

Gender: Patient/guardian checks appropriate box.

If less than 18, Guardian's Name: Guardian's full name is entered.

Are you allergic to any medications or eggs? Patient/guardian checks appropriate box. If yes, patient/guardian lists allergies to medications/eggs and type of allergic reaction.

#### Risk Criteria:

The Primary Care Provider or designee completes the risk criteria for the patient. Appropriate boxes are checked.

If the Risk Criteria section is completed at the DHEC Mass Immunization Clinic, the MD/APRN signs their legal signature and lists their license number.

If the Risk Criteria section is completed by private provider and the individual is then referred to a DHEC Mass Immunization Clinic, the private provider (MD/APRN) must sign their legal signature and list their license number.

If the Risk Criteria section is completed by private provider and the individual receives vaccine by that same private provider, a signature is not needed.

#### Vaccine Administration:

Dose 1:

Date: Vaccine provider enters month/day/year.

Vaccine Name: Vaccine provider enters vaccine name.

Manufacturer: Vaccine provider enters vaccine manufacturer.

Lot #: Vaccine provider enters vaccine lot number.

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DHEC/Immz Div/PanFlu Approval date (MOC) 8/3/2006 Page 41 of 79 Effective date 10/16/06 Exp. Date: Vaccine provider enters vaccine expiration date.

Injection Site: Vaccine provider enters injection site.

Injection Route: Vaccine provider enters injection route.

VIS Date: Vaccine provider enters VIS date.

Provider Name/Site: Person who administers the vaccine enters legal signature, including credentials and office/clinic

name.

Provider Address: Vaccine provider enters their mailing address. Label/stamp can be used.

Dose 2:

Note: If a second dose is needed, the second column of the form will be used.

Date: Vaccine provider enters month/day/year.

Vaccine Name: Vaccine provider enters vaccine name.

Manufacturer: Vaccine provider enters vaccine manufacturer.

Lot #: Vaccine provider enters vaccine lot number.

**Exp. Date:** Vaccine provider enters vaccine expiration date.

Injection Site: Vaccine provider enters injection site.

Injection Route: Vaccine provider enters injection route.

VIS Date: Vaccine provider enters VIS date.

Provider Name/Site: Person who administers the vaccine enters legal signature, including credentials and office/clinic

name.

Provider Address: Vaccine provider enters their mailing address. Label/stamp can be used.

#### OFFICE MECHANICS AND FILING:

This original (white copy) should be kept by the primary care provider in the patient's medical record. If DHEC is the provider, the form will be retained in a batch file according to the Records Management User's Manual. If the patient is a DHEC employee and the immunization is given in a DHEC clinic, the form should be filed in the employee health record. The DHEC Copy (yellow) will be given/mailed to the DHEC Regional Immunization Program Manager for data entry into the Pandemic Influenza reporting system. The primary care provider should submit the forms to the DHEC Regional Immunization Program Manager or designee on a daily/weekly basis. The Patient Copy (pink) should be given to the patient.

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## Appendix F – VAERS Training Module

The <u>Vaccine Adverse Event Reporting System (VAERS)</u> is a passive surveillance system for safety after immunization. It is a cooperative program of both the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). This passive surveillance system: (1) detects new, unusual, or rare vaccine adverse events; (2) monitors increases in known adverse events; (3) determines client risk factors for particular adverse events; (4) identifies vaccine lots with increased numbers or types of reported events; and (5) assesses the safety of newly licensed vaccines. See DHEC Health Services Policy, Immunization-Reporting Adverse Events After Vaccination (VAERS Documentation) (put in policy hyperlink)

The VAERS form is designed to capture important information about adverse events that may be caused or associated with receipt of a vaccine (see VAERS Form and Directions for Completing Form). All information received or reported about an adverse event must remain confidential.

When a complaint or report of an adverse event associated with a non-IND pandemic influenza vaccine is received:

- A VAERS form must be completed in full online (http://vaers.hhs.gov/) by the designated trained regional staff.
  - All pertinent additional information such as physician/emergency department/hospital record including laboratory and radiologic results associated with the event should be added to the VAERS report.
  - Questions concerning form completion can be directed to the VAERS On-line Help (https://secure.vaers.org/VaersHelp.html) or DHEC Immunization Division nurse consultant designee.
- The completed form will be reviewed by the Regional Medical Director or physician designee in a timely manner to determine the following:
  - o Completeness of data
  - o Possible association of event with vaccine
  - Whether the vaccinee should receive additional medical care (if not yet received)
  - o Whether the vaccinee should receive a second dose of pandemic influenza vaccine (if required)
- After review by the Regional Medical Director or physician designee, all VAERS reports that meet the following criteria must be submitted in hard copy to the DHEC Immunization Division nurse consultant designee:
  - o the client died

- o had a life-threatening illness
- o required emergency room/doctor visit
- o required hospitalization
- o resulted in prolongation of hospitalization
- o resulted in permanent disability
- Should any VAERS report(s) signal a serious concern regarding the safety of the pandemic influenza vaccine, the DHEC Immunization Division must be notified immediately by phone.
   If deemed necessary, appropriate authorities at CDC and FDA will be notified of the concern.

| P.O. Box 1100   | EVENT REPORTIN<br>Information 1-800-822-7<br>, Rockville, MD 20849-11<br>ITY KEPT CONFIDENT | 7967<br>100  | VAERS Nu  | mber   |
|---|---|--|---|--|
| Patient Name:   | Vaccine administered by   | (Name):  | Form comp   | oleted by (Name):  |
| Last First M.I.  Address  | Responsible Physician Facility Name/Address   |  | to Patient  | □ Vaccine Provider □ Patient/Parent □ Manufacturer □ Other different from patient or provider)   |
| City State Zip Telephone no. ()   | Telephone no. ()  |  |   | State Zip  |
| State 2. County where administered  | 3. Date of birth mm dd yy   | 4. Patient age   | 5. Sex  | 6. Date form completed   |
| 7. Describe adverse events(s) (symptoms, signs,   | ime course) and treatment, if a   | any  | ☐ Patient die ☐ Life threate ☐ Required e ☐ Required i ☐ Resulted i | ening illness mm dd yy /<br>emergency room/doctor visit<br>nospitalization (days)<br>n prolongation of hospitalization<br>n permanent disability |
| 9. Patient recovered YES NO UNK   | NOWN  |  | 10. Date of va  | ccination 11 Adverse event onset   |
| 12. Relevant diagnostic tests/laboratory data   |   |  | mm dd   | yy AM  |
| Vaccine (type)  Ma a.  b.  c.  d.   | nufacturer Lo   | ot number  | Rout  | No. Previous Doses   |
| 14. Any other vaccinations within 4 weeks prior to the Vaccine (type)  a b                                  | Lot number  | Route/Site   | No. Predose   |  |
| 15. Vaccinated at: ☐ Private doctor's office/hospital ☐ Military ☐ Public health clinic/hospital ☐ Other/ui | clinic/hospital  Private f  |  | is  | Other medications  |
| 18. Illness at time of vaccination (specify)  | 19. Pre-existing physicia   | n-diagnosed allergies, b                                 | irth defects, m   | edical conditions (specify)  |
| 20. Have you reported ☐ No ☐ this adverse event   | To health department  | Only<br>2. Birth weight                                  | y for children  | 5 and under 23. No. of brothers and sisters  |
| previously?   | To manufacturer   | lb   | oz.   |  |
|   |   | nly for reports submitte<br>4. Mfr./imm. proj. report n  |   | cturer/immunization project  Date received by mfr./imm.proj.   |
| ☐ In patient ☐ In brother or sister  Health care providers and manufacturers are required by                |   | 5. 15 day report?  Yes No eactions to vaccines listed in | ι   | Report type  Initial Follow-Up   |

## DIRECTIONS FOR COMPLETING VAERS FORM (Additional pages may be attached if more space is needed)

#### **GENERAL:**

- Use a separate form for each client. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible.
   Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting
  for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a client for a suspected
  adverse event should notify the VA and provide the information about the adverse event to allow
  the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of the adverse event following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccine or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front and back on same sheet).

#### SPECIFIC INSTRUCTIONS:

Form Completed By: To be used by parents' guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the client or the health professional who administered the vaccine.

| Item 7: | Describe the suspected adverse event. Such things as temperature, local and general |
|---------|---|
|         | signs and symptoms, time course, duration of symptoms, diagnosis, treatment and     |
|         | recovery should be noted.   |

- Item 9: Check "YES" if the client's health condition is the same as it was prior to the vaccine, "NO" if the client has not returned to the pre-vaccination state of health, or "UNKNOWN" if the client's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If and 11: you do not know the exact time, please indicate "AM" OR "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the client received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the client's insurance.
- Item 17: List any prescription or non-prescription medications the client was taking when the vaccine(s) was given.
- Item 18: List any short-term illnesses the client had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defect, medical conditions (including developmental and/or neurological disorders) for the client.
- Item 21: List any suspected adverse event the client, or the client's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the client has reacted to more than one prior to vaccine, use additional pages to explain completely. For the onset age of a client, provide the age in months if less than two years old.
- Item 26: This space if for manufacturers' use only.

#### **PRINTING INSTRUCTIONS:**

- a. Upon completion of the form online, left click on the SUBMIT tab.b. The completed form will be displayed with an assigned VAERS tracking number.
- c. Left click on FILE and choose PRINT to obtain a copy to be filed in the client record.

## Appendix H – Pandemic Influenza Vaccine Chain of Custody/Temperature Monitoring Form/Instructions

#### Pandemic Influenza Vaccine Chain of Custody/Temperature Monitoring Form

S. C. Dept. of Health & Environmental Control

Tel: 800-277-4687 Fax: 803-898-0318

Bureau of Disease Control Immunization Division 1751 Calhoun Street, Columbia SC 29201

| Region :           |      | Cou  | nty:        | # Vials:    |                   |
|--------------------|------|------|-------------|-------------|-------------------|
| Address:           |      | Pho  | one:        | Lot # :     |                   |
|                    |      | Con  | tact:       | Date :      |                   |
| Relinquished By    | Date | Time | Temperature | Received By | Other Information |
|                    |      |      |             |             |                   |
|                    |      |      |             |             |                   |
|                    |      |      |             |             |                   |
|                    |      |      |             |             |                   |
|                    |      |      |             |             |                   |
|                    |      |      |             |             |                   |
|                    |      |      |             |             |                   |
| FINAL DISPOSITION: |      |      |             |             | 12                |
|                    |      |      |             |             |                   |
|                    |      |      |             |             |                   |

- 1. Provide essential contact information in spaces provided at top of form.
- 2. Record date/time, temperature and persons involved in transfer each time vaccine is moved.
- 3. Storage temperature is to be monitored at all times, and recorded twice daily on temperature log.
- 4. Document description of final disposition.
- 5. Retain a copy of this document for your records, signed original must accompany vaccine and is returned to the Immunization Division upon completion.

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South Carolina Department of Health & Environmental Control

# SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL PANDEMIC INFLUENZA VACCINE CHAIN OF CUSTODY/ TEMPERATURE MONITORING FORM Instructions for Completing

#### PURPOSE:

The purpose of the PANDEMIC INFLUENZA VACCINE CHAIN OF CUSTODY / TEMPERATURE MONITORING FORM is to provide a document to be used by persons transferring pandemic influenza vaccine to record persons involved and temperature during transfer and final disposition of pandemic influenza vaccine.

#### ITEM-BY-ITEM INSTRUCTIONS:

- 1. Original form must accompany vaccine throughout process from initial to final destination.
- Person initiating transfer of vaccine should complete essential contact information: Region, Address, County, Phone, Contact, #Vials, Lot#, Date.
- 3. Record date/ time, temperature at each transfer and persons involved in each transfer of vaccine.
- 4. Complete the Final Disposition section when vaccine reaches storage destination.
- Sign form.
- 6. When form is completed:
  - Retain a copy for records at place of Final Disposition
  - Send the original form to the DHEC Immunization Division, Box 101106, Columbia, SC 29211

#### OFFICE MECHANICS AND FILING:

- The PANDEMIC INFLUENZA VACCINE CHAIN OF CUSTODY/TEMPERATURE MONITORING FORM can be obtained by:
  - (a) calling the DHEC Immunization Division at (803) 898-0460/ (800) 277-4687 or
  - (b) accessing the RIMS system [DHEC Regions only].
- The completed original PANDEMIC INFLUENZA VACCINE CHAIN OF CUSTODY/ TEMPERATURE MONITORING FORM is filed by Region in the DHEC Immunization Division Pandemic Influenza file.
- Recommended retention time for control records (PANDEMIC INFLUENZA VACCINE CHAIN OF CUSTODY/ TEMPERATURE MONITORING FORM) will be in accordance with CDC guidance.

## Appendix I – Pandemic Influenza Order Form/Instructions



#### PANDEMIC INFLUENZA VACCINE ORDER FORM

FAX TO: (803) 898-0318 OR MAIL TO: DHEC IMMUNIZATION DIVISION BOX 101106 COLUMBIA, SC 29211

INSTRUCTIONS: 1) Provide your shipping address. Notify us in writing (by fax or mail) of any change in provider information or contact person. 2) Enter the number of **Pandemic Influenza** vaccine doses you currently have in your inventory in the "Number of Doses In Stock" column. 3) Enter "Lot Number" of the doses in stock. 4) Enter "Expiration Date" of doses in stock. 5) Enter the number of doses requested in the "Number Doses Requested" column. 6) Check any weekday you cannot receive vaccine shipments (located at the bottom of the page). 7) Sign, date and fax or mail in the Vaccine Order. NOTE: For assistance call 1-800-27-SHOTS or 803-898-0460. Thank you

| mail in the Vacci | ne Order.  | NOTE: For assista   | nce call 1-800-27- | -SHOTS or 803-898-0460.     | īhank you.        |
|-------------------|------------|---------------------|--------------------|-----------------------------|-------------------|
| Practice/Facility | <i>r</i> : |                     |                    |                             |                   |
| Address:          |            |                     |                    |                             |                   |
| Phone #:          |            |                     |                    |                             |                   |
| Contact Person    | :          |                     |                    |                             |                   |
| Notes:            |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            | Pandem              | ic Influenza V     | accine Inventory            |                   |
| Number of Dose    | s In Stock | Lot Nun             | nber               | Expiration Date             | # Doses Requested |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            |                     |                    |                             |                   |
|                   |            | Check The Following | Days Practice Car  | nnot Receive Vaccine Shipme |                   |
| ☐ Monday          | [          | □ Tuesday           | □ Wednesday        | ☐ Thursday                  | □ Friday          |
| Signature:        |            |                     |                    | D                           | ate: / /          |

DHEC 1160 (09/2006)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

## SOUTH CAROLINDA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL PANDEMIC INFLUENZA VACCINE ORDER FORM Instructions for Completing

#### PURPOSE:

The purpose of the PANDEMIC INFLUENZA VACCINE ORDER FORM is to provide a document to be used by persons ordering pandemic influenza vaccine. Information including current pandemic influenza vaccine inventory and documentation of when practice is unavailable for vaccine delivery is also obtained on this form.

#### ITEM-BY-ITEM INSTRUCTIONS:

- Provider requesting pandemic influenza vaccine must complete essential information including: practice/facility, address, phone number and contact person.
- If there is a change in the essential information, the DHEC Immunization Division must be notified in writing (by fax or mail).
- 3. Enter the "Number of Doses in Stock" of pandemic influenza vaccine currently located at practice site.
- 4. Enter the "Lot Number" of the pandemic influenza vaccine doses in stock.
- 5. Enter the "Expiration Date" of the pandemic influenza vaccine doses in stock.
- 6. Enter the "Number of Doses Requested" of pandemic influenza vaccine for the practice site.
- 7. Check any weekday the practice cannot receive vaccine shipments.
- 8. Sign and date the form.
- 9. When the form is completed:
  - Send to DHEC Immunization Division, Box 101106, Columbia, SC 29211 or
  - Fax to DHEC Immunization Division (803) 898-0318.

#### OFFICE MECHANICS AND FILING:

- The PANDEMIC INFLUENZA VACCINE ORDER FORM can be obtained by:
  - (a) calling the DHEC Immunization Division at (803) 898-0460/ (800) 277-4687 or
  - (b) accessing the RIMS system [DHEC Regions only].
- The completed original PANDEMIC INFLUENZA VACCINE ORDER FORM is filed by Region in the DHEC Immunization Division Pandemic Influenza file.
- Recommended retention time for control records (PANDEMIC INFLUENZA VACCINE ORDER FORM) will be in accordance with CDC guidance.

## Appendix J – Pandemic Influenza Vaccine Temperature Log/Instructions

| D                        | X .            | E<br>STECT PRO    | C      | ,  | Site: |    |    |    |    |    | PA |    |    | 1  | FLU<br>mmu | nizat | ion [ | Divisi | on |    | RE I |    |    |    | M  | onth/ | Year: |    |    | Days 1-15 |                  |        |  |  |
|--------------------------|----------------|-------------------|--------|--|-------|----|----|----|----|----|----|----|----|----|------------|-------|-------|--------|----|----|------|----|----|----|----|-------|-------|----|----|-----------|------------------|--------|--|--|
| pr                       | n (colun       |                   | ne app | bur initials and under the corresponding day of the month enter the time you monitor the temperature of your refrigerator/freezer. Place an ". propriate temperature (row). If the temperature is in the red area, store the vaccine under proper conditions immediately and contact and the contact area. |       |    |    |    |    |    |    |    |    |    |            |       |       |        |    |    |      |    |    |    |    |       |       |    |    |           |                  |        |  |  |
|                          | li             | nitials:<br>Date: |        | ř.   |       | 2  |    | 3  | _  | 4  | -  | 5  |    | 6  | <u> </u>   | 7     | _     | В      |    | 9  | 1    | 0  | 1  | 1  | 1  | 2     | 1     | 3  | 14 | 4         | 1                | 5      |  |  |
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| l                        | <u>&gt;</u> 49 |                   |        |  |       |    |    |    |    |    |    |    |    |    |            |       |       |        |    |    |      |    |    |    |    |       |       |    |    |           |                  |        |  |  |
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| Refrigerator Temperature | 43             | 6                 | 9      |  |       |    | _  |    | _  |    |    |    |    | 4  |            |       |       |        |    |    |      |    |    |    |    |       | _     |    |    |           | Н                |        |  |  |
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| tor                      | 41             | 5                 | 0      |  |       |    | -  |    |    |    |    |    |    |    |            |       | -     |        |    |    |      |    | _  | _  |    | -     |       |    |    |           | H                |        |  |  |
| ger                      | 40<br>39       | 4                 |        |  | -     |    |    |    |    |    |    | -  |    |    | _          |       |       |        |    |    | -    |    | -  |    |    | -     |       |    |    | $\vdash$  |                  |        |  |  |
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| 4                        | 37             | 3                 |        |  |       |    |    |    | _  |    |    |    |    |    |            |       |       |        |    |    |      |    |    |    |    |       |       |    |    |           |                  |        |  |  |
| ł                        | 36             |                   |        |  |       |    |    |    |    |    |    |    |    |    |            |       |       |        |    |    |      |    |    | -  | -  | _     |       |    | -  |           |                  |        |  |  |
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|---------|------|--------|-------|
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## PANDEMIC INFLUENZA TEMPERATURE LOG

Immunization Division

| Days 16 | 5-3 |
|---------|-----|
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| era                      | 39             | 4          |    |    |    |    |    |     |    |     |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |     |     |    |    |    |    |    |
| frig                     | 38             | 3          |    |    |    |    |    |     |    |     |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |     |     |    |    |    |    |    |
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DHEC 1159 (9/2006)

South Carolina Department of Health & Environmental Control

## SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL PANDEMIC INFLUENZA TEMPERATURE LOG (Instructions for Completing)

#### PURPOSE:

The purpose of this PANDEMIC INFLUENZA TEMPERATURE LOG is to provide a form that can be used for documentation twice daily monitoring of temperatures used to store pandemic influenza vaccine.

#### ITEM-BY-ITEM INSTRUCTIONS:

- Enter the site, location, and the month and year the temperature is being checked at the top of the log.
- 2. Enter the initials of the person checking the temperature.
- 3. Enter the exact time the temperature is checked under the appropriate day of the month column and in the appropriate am or pm column.

#### OFFICE MECHANICS AND FILING:

- The PANDEMIC INFLUENZA TEMPARTURE LOG can be obtained by:
  - (a) calling the DHEC Immunization Division at (803) 898-0460/ (800) 277-4687 or
  - (b) accessing the RIMS system [DHEC Regions only].
- Recommended retention time for laboratory control records (PANDEMIC INFLUENZA TEMPERATURE LOG) in accordance with CDC guidance.

## Appendix K – Job Action Sheets

## Clinic Manager

| Site:                 |             |
|-----------------------|-------------|
| Position Assigned To: |             |
| Date of Assignment:   | Shift Time: |
| Job Shift(s):         |             |
| You Report To:        |             |

Mission:

Will serve as the mass vaccination clinic lead person and has ultimate responsibility for all clinic operations and inquiries. Will be responsible for making all clinic operational decisions, overseeing staff, and ensuring the clinic workflow is running efficiently.

Qualifications: Good organizational skills and health care management experience, physically able to stand for long periods of time, able to carry required items (ie. questionnaires, etc), received required training, prior vaccination for pandemic influenza, signature of DHEC Volunteer Agreement (if DHEC volunteer).

#### **Equipment:**

- Roster of clinic staff/ volunteers.
- Communication device with other staff (phone, radio, etc)
- Contact numbers of station leaders/managers
- Other equipment deemed necessary by Regional staff

#### **Immediate Duties:**

- Arrive at assigned site 2.5 hours prior to start time and check in.
- Read Job Action Sheet for assigned duties.
- Review job tasks of all staff.
- Meet with staff and review roles 1-2 hours prior to start time.
- Review security plans with security personnel and Greeters in anticipation of any security problems.

- Verify the physician "on call" and appropriate contact information.
- Confirm with DHEC Public Health Regional Supply Manager at least 1.5 hours prior to start time that all equipment and supplies are on-site and facility is ready for use.
- Confirm at least 1 hour prior to start time that staffing is adequate.
- Provide access list (staff roster) to clinic Greeter.
- Maintain contact with clinic Public Information Liaison to refer all media inquiries.

## **Ongoing Duties:**

- Develop/maintain a signature list of all medical screeners and vaccinators.
- Maintain contact with DHEC Public Health Regional vaccination clinic Supply Manager to update on clinic progress.
- Assign Vaccination Clinic staff to the critical flow areas of the clinic operation and adjust as necessary.
- Address staff concerns.
- Ensure all stations are equipped and ready for operation.
- Monitor clinic flow and identify/eliminate problem areas.
- Refer media inquiries to Public Information Liaison.
- Respond to security concerns in coordination with Security staff as appropriate.

- Supervise final site clean-up.
- Debrief DHEC Public Health Regional Supply Manager to assess supply needs
- Debrief Regional Incident Commander on overall clinic outcomes.
- In conjunction with Supply Manager, confirm with facility security staff regarding the status of the building security and ensure that vaccines are securely stored.
- Check out with appropriate supervising authorities.
- Participate in scheduled debriefing sessions

## **Greeter for Parking Area**

| Position Assigned To:  Date of Assignment:  Job Shift(s):  You Report To: | Site:                 |             |  |  |  |
|---|-----------------------|-------------|--|--|--|
| Job Shift(s):   | Position Assigned To: |             |  |  |  |
|   | Date of Assignment:   | Shift Time: |  |  |  |
| You Report To:  | Job Shift(s):         |             |  |  |  |
| 104 Report 10.  | You Report To:        |             |  |  |  |

Mission: Greet potential vaccinees before they exit car/bus; provide initial

screening of vaccinees and initial orientation of intake process.

Qualifications: Non-licensed; health-care background preferred; public

speaking and good communication skills, physically able to stand for long periods of time, able to carry required items (ie. questionnaires, etc), received required training, prior vaccination for pandemic influenza, signature of DHEC

Volunteer Agreement (if DHEC volunteer).

## **Equipment:**

- Roster of clinic staff
- Roster/schedule of clients to receive vaccine (if applicable)
- Flowchart of clinic operation
- Pens
- Clipboards
- Watch/clock
- Communication device with other staff (phone, radio, etc)
- Contact numbers of station leaders/managers
- Screening forms

#### **Immediate Duties:**

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager.
- Read Job Action Sheet for assigned duties.
- Receive orientation/training.
- Assist in setting up clinic operation.

- Secure a current list of clinic staff from Clinic Manager.
- Direct staff to separate clinic access/entry, if deemed appropriate.
- Obtain contact information for the clinic Public Information Liaison for media inquiries.
- Review security plans with security personnel and Clinic Manager in anticipation of any security problems.
- Obtain supplies/equipment

## **Ongoing Duties:**

- Greet potential vaccinees before they exit car/bus.
- In conjunction with security, ensure only authorized persons enter parking area.
- Provide screening questionnaire to distinguish signs and symptoms suggestive of pandemic influenza infection AND prior exposure to pandemic influenza.
- Direct persons who complete questionnaire and have signs/symptoms
   or prior exposure to pandemic influenza to a separate designated location.
- Monitor the identification system staff granted access to the emergency clinic will have appropriate identification badges (i.e. Health Agency ID, photo ID, etc.). Suggested that staff have different access/entry than potential vaccinees.
- If an unauthorized person enters, notify the Clinic Manager and security.
- Direct persons who complete questionnaire without signs and symptoms suggestive of pandemic influenza or prior exposure to designated vaccination site.
- Direct all media inquiries to the Public Information Liaison assigned to the clinic.
- Inform clients of the resources available to assist them (i.e. language translation assistance, assistance for people with disabilities, mental health consultation, etc.).
- Alert appropriate clinic staff of any special needs clients entering clinic, so that the necessary resources can be prepared.

- Clear and clean the greeting station at the conclusion of the clinic operation
- Assist with final site clean-up
- Check out with Clinic Manager
- Participate in scheduled debriefing session

## **Greeter(s) for Designated Vaccination Site**

| Site:                 |             |
|-----------------------|-------------|
| Position Assigned To: |             |
| Date of Assignment:   | Shift Time: |
| Job Shift(s):         |             |
| You Report To:        |             |

Mission: Provide orientation information and guidance regarding clinic

flow to potential vaccinees.

Qualifications: Non-licensed with some health care background preferred,

public speaking and good communication skills, received required training, prior vaccination for pandemic influenza,

signature of DHEC Volunteer Agreement (if DHEC

volunteer).

## **Equipment:**

- Roster of clinic staff
- Roster/schedule of clients to receive vaccine (if applicable)
- Flowchart of clinic operation.
- Pens
- Clipboards
- Watch/clock
- Communication device with other staff (phone, radio, etc)
- Contact numbers of station leaders/managers
- Client education materials

#### Immediate Duties:

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager.
- Read Job Action Sheet for assigned duties.
- Receive orientation/ training.
- Assist in setting up clinic operation.
- Secure a current list of clinic staff from Clinic Manager.

- Direct staff to separate clinic access/entry, if deemed appropriate.
- Obtain contact information for the clinic Public Information Liaison for media inquiries.
- Review security response plans with security personnel and Clinic Manager in anticipation of any security problems.
- Obtain supplies and equipment

## **Ongoing Duties:**

- In conjunction with security, ensure only pre-screened persons enter designated vaccination site.
- Ensure that only staff with appropriate identification are granted access to the vaccination clinic.
- Direct all media inquiries to the Public Information Liaison assigned to the clinic.
- Facilitate client education regarding clinic flow.
- Provide each vaccinee information describing pandemic influenza, the vaccination process and potential adverse events. Consider separate station for vaccinee education, as deemed appropriate.
- Inform clients of the resources available to assist them (i.e. interpretation/ translation assistance, assistance for people with disabilities, mental health consultation, etc.).
- Alert appropriate clinic staff of any special needs clients entering clinic, so that the necessary resources can be prepared.
- Direct each potential vaccinee to the registration station or to medical assistance if vaccinee has questions.
- Alert psychosocial team member of any distressed, upset and anxious clients or refer person(s) to the consultation area.

- Clear and clean the greeting station at the conclusion of the clinic operation.
- Assist with final site clean-up.
- Check out with Clinic Manager.
- Participate in scheduled debriefing session

## Registration

| Site:                 |             |  |  |  |
|-----------------------|-------------|--|--|--|
| Position Assigned To: |             |  |  |  |
| Date of Assignment:   | Shift Time: |  |  |  |
| Job Shift(s):         |             |  |  |  |
| You Report To:        |             |  |  |  |

Mission: Assure completeness and accuracy of each client's

screening/consent/declination documents

Qualifications: Basic clerical and computer/organizational skills, received

required training, prior vaccination for pandemic influenza,

signature of DHEC Volunteer Agreement (if DHEC

volunteer).

## **Equipment:**

- Pens
- Clipboards
- Watch/clock
- Computer with appropriate software
- Registration form
- Communication device with other staff (phone, radio, etc)
- Contact numbers of station leaders/managers
- □ Flowchart of clinic operation
- Roster/schedule of clients to receive vaccine (if applicable)

#### Immediate Duties:

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager
- Read Job Action Sheet for assigned duties
- Receive orientation/training
- Assist in setting up clinic operation
- Ensure a sufficient number of clipboard packets are prepared and available
- Obtain supplies/equipment

## **Ongoing Duties:**

- Provide forms to vaccinees and address any questions regarding completion of forms.
- Complete registration process with potential vaccinee as appropriate.
   May include providing potential vaccinee with a Client Vaccination
   Number (PVN) and corresponding client tracking labels/stickers.
- Review each client's documents for completeness, accuracy and legibility.
- Assist clients in completing documents, as needed.
- Be available to answer any questions regarding form completion, as needed
- All medical questions should be referred to the Medical Screeners for clarification.
- When client completes registration, direct vaccinee to the medical screening station.
- Alert a psychosocial team member of any distressed, upset and anxious clients or refer person(s) to the consultation area.

- Re-pack supplies conveniently for next clinic and notify Supply Manager of supplies needed..
- Assist with final site clean-up.
- Check out with Clinic Manager.
- Participate in scheduled debriefing session

#### **Medical Screener**

| Site:                 |             |  |  |  |
|-----------------------|-------------|--|--|--|
| Position Assigned To: |             |  |  |  |
| Date of Assignment:   | Shift Time: |  |  |  |
| Job Shift(s):         |             |  |  |  |
| You Report To:        |             |  |  |  |
|                       |             |  |  |  |

Mission: Review each potential vaccinee's medical history and assess for

any contraindications to vaccine.

NOTE: A public health physician must be "on call" for any questions and

final recommendations/ decisions.

Qualifications: Licensed MD or APRN, physically able to stand for long

periods of time, received required training, prior

vaccination for pandemic influenza, signature of DHEC

Volunteer Agreement (if DHEC volunteer).

## **Equipment:**

- Training toolkit notebook
- Educational material
- Appropriate forms
- Private/confidential area.
- Pens
- Notepads
- □ Contact numbers of physician on-call and station leaders Must have access to:
- Phone.
- Resources (Physicians Desk Reference Book, Medical Dictionary and others as identified)
- Communication device with other staff (phone, radio, etc)

#### Immediate Duties:

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager.
- Read Job Action Sheet for assigned duties
- Receive orientation/training. Training must include an understanding of the disease process as well as contraindications, side effects (if known).
- Complete the Pandemic Influenza Vaccination form, as appropriate.
- Assist in setting up the clinic operation and ensure appropriate equipment/ supplies are available to all screeners.

## **Ongoing Duties:**

- Confirm the client is eligible to receive the vaccine.
- Confer with physician "on call" if further consultation/evaluation regarding eligibility is needed.
- Answer any medical questions concerning vaccine and reactions.
- If no contraindications, direct client to vaccination station waiting area.
- □ For non-English reading/speaking clients, contact interpreter and obtain information necessary to complete screening form.
- If potiential vaccinee decides not to receive vaccine, have client sign declination, sign as witness, collect forms and direct to designated exit.
- Alert a psychosocial team member of any distressed, upset and anxious clients or refer person(s) to the consultation area.
- Request additional forms and other supplies from Supply Manager.

- Prepare Medical Screening station for next clinic.
- Assist with final site clean-up.
- Check out with Clinic Manager.
- Participate in scheduled debriefing sessions.

#### **Vaccinator**

| Site:                 |             |  |  |
|-----------------------|-------------|--|--|
| Position Assigned To: |             |  |  |
| Date of Assignment:   | Shift Time: |  |  |
| Job Shift(s):         |             |  |  |
| You Report To:        |             |  |  |
|                       |             |  |  |

Mission: Confirm appropriate documentation prior to injection; administer

vaccine

Qualifications: Licensed medical professional, physically able to stand for

long periods of time, received required training, prior vaccination for pandemic influenza, signature of DHEC

Volunteer Agreement (if DHEC volunteer).

## **Equipment:**

- Pandemic Influenza vaccine
- Diluent (if applicable)
- Syringes/needles
- Biohazard Sharps container
- Biohazard trash container
- Non-latex gloves
- Waterless antiseptic handwash
- Antibacterial hand washing solution
- Hand lotion
- Gauze/cotton balls
- Tissues
- Alcohol pads
- Hypoallergenic tape
- Bandaids
- Paper towels
- □ 1:10 Bleach solution in spray bottle
- Sharpie permanent marker

- Pen
- Emergency kit/cart
- Appropriate forms

Must have access to:

- Pandemic Influenza administration supplies.
- DHEC Standing Order for Pandemic Influenza vaccination
- DHEC Emergency Standing Orders
- DHEC Pandemic Influenza Vaccination Policy
- Contact numbers of physician on-call and station leaders
- DHEC Pandemic Influenza Vaccination form
- Communication device with other staff (phone, radio, etc)

#### **Immediate Duties:**

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager.
- Read Job Action Sheet for assigned duties.
- Set up vaccination station.
- Obtain orientation regarding specific tasks and special instructions for specific type of vaccine being used.
- Review printed/other materials on injection administration.

## **Ongoing Duties:**

- Answer final client questions.
- Review vaccinee history for contraindications, client and medical screener's signature
- Prepare syringe for vaccine administration, as needed.
- Administer vaccination.
- Observe for immediate reactions/complications.
- Request Emergency Medical Staff assistance, as needed.
- Ensure appropriate documentation: vaccine type, vaccine lot number (as printed on vaccine vial), vaccine manufacturer, date of vaccination, site of vaccination, person administering vaccine, VIS date.
- Once completed, route Pandemic Influenza Vaccination form to records management/data processing.
- Direct vaccine recipients to exit counseling station.
- Alert psychosocial team member of any distressed, upset and anxious clients or refer person(s) to the consultation area.
- Request additional forms and other supplies from Supply Manager.

- □ Repack supplies conveniently for next clinic.
- Clear and clean station area.
- Assist with final site clean-up.
- □ Check out with Clinic Manager.
- Participate in scheduled debriefing sessions

#### **Exit Counselor**

| Site:                 |             |  |  |  |
|-----------------------|-------------|--|--|--|
| Position Assigned To: |             |  |  |  |
| Date of Assignment:   | Shift Time: |  |  |  |
| Job Shift(s):         |             |  |  |  |
| You Report To:        |             |  |  |  |

Mission: Provide information regarding revaccination (if applicable) and

potential vaccine adverse events.

Qualifications: Basic clerical, communication and organizational skills;

received required training, prior vaccination for pandemic influenza, signature of DHEC Volunteer Agreement (if

DHEC volunteer).

## **Equipment:**

- Pens
- Information handouts (such as documentation of receipt of vaccine)
- Communication device with other staff (phone, radio, etc)
- Contact numbers of station leaders/managers

#### **Immediate Duties:**

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager.
- Read Job Action Sheet for assigned duties
- Receive orientation/training.
- Assist with set-up of consultation area.
- Request needed supplies from Supply Manager.

#### **Ongoing Duties:**

- Provide appropriate client counseling for revaccination (if applicable) and adverse events
- Direct Client to designated exit point.

- Clean up and prepare consultation station for next clinic.
- Assist with final site clean-up.
- Check out with Clinic Manager.
- Participate in scheduled debriefing sessions.

### Interpreter

| Site:                 |             |
|-----------------------|-------------|
| Position Assigned To: |             |
| Date of Assignment:   | Shift Time: |
| Job Shift(s):         |             |
| You Report To:        |             |

**Mission:** Provide interpretation/translation services for non-English

speaking clients throughout the process.

Qualifications: Non-medical, proficiency in both English and another

language for interpretation/translation, physically able to stand for long periods of time, received required training, prior vaccination for pandemic influenza, signature of

DHEC Volunteer Agreement (if DHEC volunteer).

### **Equipment:**

- Copies of all forms and educational materials in English
- Copies of all forms and educational materials in other languages
- Pens
- Clipboards
- Notepad
- Language dictionary.
- Communication device with other staff (phone, radio, etc)
- Contact numbers of station leaders/managers
- Flowchart of clinic operation

#### Immediate Duties:

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager.
- Read Job Action Sheet for assigned duties
- Receive orientation/ training
- Review and become familiar with all forms and educational materials to enable easier translation.

- □ Assist/provide translation of forms and materials, if possible.
- Maintain contact with clinic staff, so they are aware of your availability to interpret.

## **Ongoing Duties:**

- Requests for interpretation may come from any staff.
- Greet the client, introduce yourself, and explain that you are there to provide interpretation/translation to help them through the clinic process.
- Interpret all verbal instructions, questions, education, and translate any written material.
- Provide assistance with forms.
- Accompany clients through each station of the clinic process.
- Alert psychosocial team member of any distressed, upset and anxious clients or refer person(s) to the consultation area.
- Request additional forms and other supplies from Supply Manager.

- Re-pack supplies conveniently for next clinic and notify Supply Manager of any supply needs.
- Assist with final site clean-up.
- Check out with Clinic Manager
- Participate in scheduled debriefing sessions

## **Data Entry**

| Site:                 |             |
|-----------------------|-------------|
| Position Assigned To: |             |
| Date of Assignment:   | Shift Time: |
| Job Shift(s):         |             |
| You Report To:        |             |

Mission: Enters designated data into the DHEC Immunization Registry or

other required data bases

Qualifications: Basic clerical/data entry and typing skills, received

required training, prior vaccination for pandemic influenza,

signature of DHEC Volunteer Agreement (if DHEC

volunteer).

## **Equipment:**

- Laptops with AC adaptors.
- External keyboards.
- External mouse
- Surge protector power strips.
- Extension cords.
- □ File box with folders identified for each participating facility
- Pens
- Notepads
- Communication device with other staff (phone, radio, etc)
- Contact numbers of station leaders/managers

#### Immediate Duties:

- Arrive at assigned site 1.5 hours prior to start time and check in with Clinic Manager.
- Read Job Action Sheet for designated duties
- Receive orientation/ training
- Assist in setting up clinic operation.

## **Ongoing Duties:**

- Enter all client data into data base, as instructed.
- □ File paper copies according to recommended guidelines.

- Assist with final site clean-up.
- □ Check out with Clinic Manager.
- Participate in scheduled debriefing sessions.

Appendix L – Sample Computer Programs to Assist with Mass Vaccination Clinic Staffing

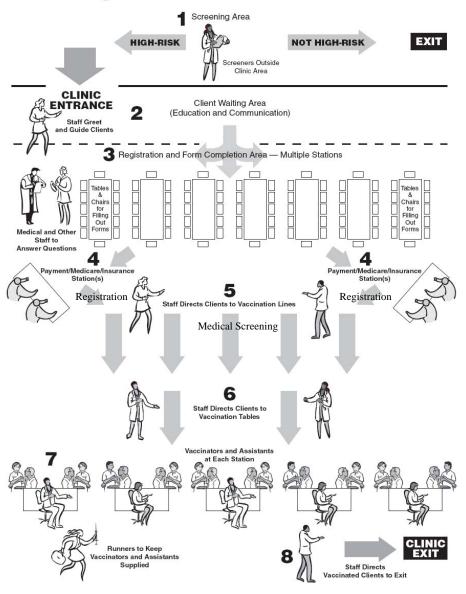
University of Maryland – Clinic Planning Model Generator <a href="http://www.isr.umd.edu/Labs/CIM/projects/clinic/">http://www.isr.umd.edu/Labs/CIM/projects/clinic/</a>

MaxiVac 1.0 and MaxiVac Alternative <a href="http://www.bt.cdc.gov/agent/smallpox/vaccination/maxi-vac/">http://www.bt.cdc.gov/agent/smallpox/vaccination/maxi-vac/</a>

Cornell University Model <a href="http://www.ahrq.gov/research/biomodel.htm">http://www.ahrq.gov/research/biomodel.htm</a>

## Appendix M – CDC High-Volume Influenza Vaccination Clinic

## **High-Volume Influenza Vaccination Clinic**



<sup>\*</sup>All stations may not be applicable to each vaccination clinic.

Appendix N-1 – Mass vaccination clinic Roster/Instructions

| D H E C                 | Mass Immunization Clinic Roster (Licensed) |            |                 |            |
|-------------------------|--|------------|-----------------|------------|
|                         |  | Date:      | Location:       |            |
| PROMOTE PROTECT PROSPER | Shift Start:                               | End:       | Clinic Manager: |            |
| Medical Screeners       |  | License #: | Vaccinators     | License #: |
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DHEC 1158 (9/2006)

South Carolina Department of Health & Environmental Control

## SOUTH CAROLINDA DEPARTMENT OF HEALTH & ENVIRONMENTAL CONTROL PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER For LICENSED PERSONS Instructions for Completing

#### PURPOSE:

The purpose of the PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for LICENSED PERSONS is to provide documentation of the names and license numbers of staff participating in a specific pandemic influenza mass immunization clinic.

#### **ITEM-BY-ITEM INSTRUCTIONS:**

- Complete the date, location, shift start and end time and clinic manager name on the PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for LICENSED PERSONS.
- 2. Enter the name of the medical screener/ vaccinator.
- 3. Enter the license number of the medical screener/ vaccinator.
- 4. During the clinic, the mass immunization clinic manager will maintain the personnel roster.
- 5. When the clinic is completed:
  - Send the form to the Immunization Program Manager for that particular region.
  - Send a copy to DHEC Immunization Division, Box 101106, Columbia, SC 29211

#### OFFICE MECHANICS AND FILING:

- The PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for LICENSED PERSONS can be obtained by:
  - (a) calling the DHEC Immunization Division at (803) 898-0460/ (800) 277-4687 or
  - (b) accessing the RIMS system [DHEC Regions only].
- The copy of the PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for LICENSED PERSONS is filed by Region in the DHEC Immunization Division Pandemic Influenza file. The region may also choose to maintain a file of the roster.
- Recommended retention time for control records (PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for LICENSED PERSONS) will be in accordance with CDC guidance.

Appendix N-2 – Mass vaccination clinic Roster/Instructions

| D H E C                  | Mass Immunization Clinic Roster (Non-Licensed) |                            |                              |                 |  |
|--------------------------|--|----------------------------|------------------------------|-----------------|--|
| PROMOTE PROTECT PROSPER  | Shift Start:                                   | Date:<br>End:              | Location:<br>Clinic Manager: |                 |  |
| Greeters<br>Parking Area |  | Greeters<br>ccination Site | Registrars                   | Exit Counselors |  |
| raiking Area             | Va   | cemation one               |                              |                 |  |
|                          |  |                            |                              |                 |  |
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| Interpreters             |  | Data Er                    | ntry                         | Other           |  |
|                          |  |                            |                              |                 |  |
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DHEC 1157 (9/2006)

South Carolina Department of Health & Environmental Control

DHEC/Immz Div/PanFlu

Approval date (MOC) 8/3/2006 Effective date 10/16/06 Page 78 of 79

# SOUTH CAROLINA DEPARTMENT OF HEALTH & ENVIRONMENTAL CONTROL PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER For NON-LICENSED PERSONS Instructions for Completing

#### PURPOSE:

The purpose of the PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for NON-LICENSED PERSONS is to provide documentation of the names of staff participating in a specific pandemic influenza mass immunization clinic.

#### ITEM-BY-ITEM INSTRUCTIONS:

- Complete the date, location, shift start and end time and clinic manager name on the PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for NON-LICENSED PERSONS.
- 2. Enter the name of the greeter, registrar, exit counselor, interpreter, data entry personnel.
- 3. If additional jobs are assigned, enter name and job title in "Other" column.
- During the clinic, the mass immunization clinic manager will maintain the personnel roster.
- 5. When the clinic is completed:
  - Send the form to the Immunization Program Manager for that particular region.
  - Send a copy to DHEC Immunization Division, Box 101106, Columbia, SC 29211

#### OFFICE MECHANICS AND FILING:

- The PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for NON-LICENSED PERSONS can be obtained by:
  - (a) calling the DHEC Immunization Division at (803) 898-0460/ (800) 277-4687 or
  - (b) accessing the RIMS system [DHEC Regions only].
- 2. The copy of the PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for NON-LICENSED PERSONS is filed by Region in the DHEC Immunization Division Pandemic Influenza file. The region may also choose to maintain a file of the roster.
- Recommended retention time for control records (PANDEMIC INFLUENZA MASS VACCINATION CLINIC ROSTER for NON-LICENSED PERSONS) will be in accordance with CDC guidance.